

US3432023 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:36:50

All time stamps listed in this document are displayed in GMT

US3432023

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 23:34:20

Generated On: 09 Jun 2021 17:36:50

[Participant ID](#)

US3432023

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

US3432023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:34:23

Generated On: 09 Jun 2021 17:36:50

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

Visit date (dd MMM yyyy)	05 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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US3432023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Date of Birth (MMM yyyy)	(b) (6) 1937
Age	83
Age Units	YEARS
Age (Derived)	83
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 23:34:22

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Date of Informed Consent (dd MMM yyyy) 5 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

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

Was participant enrolled in the study? Yes ☒
No ☐

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

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

If Yes, previous participant number _____
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 23:34:22

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 23:34:22

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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) 15 Feb 2021 23:34:22

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	MILD DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	MONOCLONAL GAMMOPATHY OF UNDETERMINED SIGNIFICANCE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	MILD RENAL FAILURE
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	CHRONIC ANEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	STROKE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 23:34:22

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Condition	PNEUMOCOCCAL PNEUMONIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	PENICILLIN ALLERGY (SERUM SICKNESS)
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	HYPOTHYROIDISM
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 (11)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	CHRONIC LOW BACK PAIN WITH INTERMITTENT FLARE
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 (12)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	HYPERTENSION (WELL CONTROLLED)
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 (13)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	PREMATURE VENTRICULAR COMPLEX
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 (15)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	CONSTIPATION
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: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	TAVR FOR AORTIC STENOSIS
Start date (dd MMM yyyy)	UN JUN 2019
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 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Condition	SEASONAL ALLERGIES
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: Vital Signs

Data signed: (b) (4) 15 Feb 2021 23:34:23

Generated On: 09 Jun 2021 17:36:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:24
Height (xxx.x)	171.1 cm
Weight (xxx.x)	77.0 kg
BMI (xxx.x)	26.30212 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	
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) 15 Feb 2021 23:34:22

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 23:34:22

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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) 15 Feb 2021 23:34:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184652

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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)	5 AUG 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:24
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)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 14:24
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)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 13:54 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 13:54

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) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	13:00 (24 HR)
Collection date and time (derived)	5 AUG 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:05	5 AUG 2020 13:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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 17:36:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 14:33

PC Open Date & Time

05 AUG 2020 14:14

PC Close Date & Time

05 AUG 2020 16:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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 98.4 °F

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

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

PC Time Stamp	06 AUG 2020 09:11
PC Open Date & Time	05 AUG 2020 17:39
PC Close Date & Time	06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

98.6 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 AUG 2020 04:04

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 08:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	09 AUG 2020 06:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 09:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 07:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 AUG 2020 09:48
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 14:34

PC Open Date & Time

05 AUG 2020 14:14

PC Close Date & Time

05 AUG 2020 16:44

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

06 AUG 2020 09:12

PC Open Date & Time

05 AUG 2020 17:39

PC Close Date & Time

06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

07 AUG 2020 04:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

08 AUG 2020 08:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

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

09 AUG 2020 06:43

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

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

10 AUG 2020 09:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

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

11 AUG 2020 07:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

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

12 AUG 2020 09:48

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 14:34
PC Open Date & Time	05 AUG 2020 14:14
PC Close Date & Time	05 AUG 2020 16:44

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 09:13
PC Open Date & Time	05 AUG 2020 17:39
PC Close Date & Time	06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 04:06
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 08:58
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 3118

EAB) (1725)

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 06:44
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 09:42
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 07:09
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 09:49
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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

Visit date (dd MMM yyyy)	02 SEP 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	VISIT2
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US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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)	02 SEP 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:06
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

13:35 (24 HR)

Collection date and time (derived)

02 SEP 2020 13:35

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	02 SEP 2020 14:07
Nasopharyngeal Swab 2	No		

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 15:17
Temperature (xxx.x)	97.6 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

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.

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	15:44 (24 HR)
Collection date and time (derived)	01 OCT 2020 15:44

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:35:11

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 15:13:42
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 13:49:18

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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	22 NOV 2020 10:22:34
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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	29 NOV 2020 12:28:12
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 14:37:32
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

15 DEC 2020 14:37:21

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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	22 DEC 2020 14:42:02
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

29 DEC 2020 06:29:13

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 14:15:49

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

11 JAN 2021 18:00:04

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 15:01:34
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

24 JAN 2021 15:02:55

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 FEB 2021 12:04:32
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 FEB 2021 03:43:14
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 FEB 2021 17:50:52
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 16:05:17
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

19 MAR 2021 15:34:05

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 21:38:03
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 APR 2021 13:43:45
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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="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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 <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"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3432023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:36:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:52:03

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:22

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments
If Contact Not Made, please provide Comments
PARTICIPANT UNABLE TO
SPEAK WITH RESEARCH TEAM
AS HE WAS IN THE HOSPITAL
AT THE TIME OF THE CALL

US3432023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT4

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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) _____

US3432023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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.

US3432023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3432023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Date of Contact	7 AUG 2020
Time of Contact	11:00
Date and Time of Contact (derived)	7 AUG 2020 11:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	7 AUG 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	37.0 C
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 AUG 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 AUG 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 AUG 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Date of Visit 7 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 7 AUG 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 AUG 2020
Day 5	No	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	SICKD1

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 AUG 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 11:47
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

US3432023

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 AUG 2020

US3432023

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

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

Visit date (dd MMM yyyy)	16 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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US3432023

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Date of updated informed consent (dd MMM yyyy)	16 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	16 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3432023

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

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

US3432023

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 10:30
Temperature (xxx.x)	37.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 11:25
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 JAN 2021

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

US3432023

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 16 JAN 2021

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 10:55

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

US3432023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	16 JAN 2021 10:30

US3432023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	10:40
Collection Date and Time (derived)	16 JAN 2021 10:40

US3432023

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag 1

OLD29 Placebo Flag 1

US3432023

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID OLD29

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3432023

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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.

US3432023

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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

PT COULD NOT COME IN, CONTACTING PT TO SEE WHEN PT COULD COME IN.

What was the study treatment? (Unblinded) _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3432023

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID OLD57

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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) _____

US3432023

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

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.

US3432023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3432023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 23:34:20

Generated On: 09 Jun 2021 17:36:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

AEID	USA-US078-2020-MRNA-1273-P30 1000001
Adverse event	POSSIBLE POLYMYALGIA RHEUMATICA
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)	20 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	21 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

24AUG20, WE RECEIVED RHEUMATOLOGY ATTENDING CONSULTATION NOTE WHO SAW PT 21AUG20 AT HOSPITAL. SPOKE W/ RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING IP. SYMPTOMS AT THAT TIME WERE MILD & THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED IP ON 5AUG20 & REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS & PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) & WEAKNESS. DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE 20AUG20, & HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

OF PREDNISONE ON 20AUG20.
FELT MUCH BETTER 21AUG20 &
DISCHARGED W/
PRESCRIPTION OF PREDNISONE
20 MG DAILY, WITH A
PLANNED TAPERING OVER 16
DAYS.

AT THIS TIME
RHEUMATOLOGIST THINKS
PMR MAY BE POSSIBLE
DIAGNOSIS. BACK PAIN
PRESENT BEFORE THE IP
ADMINISTRATION, BUT
POLYMYALGIA AND
WEAKNESS DEVELOPED AFTER
VACCINE ADMINISTRATION.
WE ARE UPDATING AE TO
INCLUDE ADDITIONAL
SYMPTOMS. GIVEN THIS
ADDITIONAL INFORMATION,
THE CONSULTATION WITH THE
TREATING RHEUMATOLOGIST,
& TIMING OF DEVELOPMENT
OF THESE SYMPTOMS IT IS
POSSIBLE THAT VACCINE MAY
HAVE CONTRIBUTED TO THE
SYMPTOMS. THUS, WE ARE
CHANGING OUR ASSESSMENT
THAT THERE MAY BE A
POSSIBLE RELATIONSHIP
BETWEEN THE
SYMPTOMATOLOGY OF PT
AND THE STUDY PRODUCT.
AS OF TODAY HE FEELS GOOD
DURING THE DAY, BUT WAKES
UP IN MORNING WITH SOME
PAIN IN THE SHOULDERS

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

AND NECK. THE PAIN GOES
AWAY APPROXIMATELY 2
HOURS AFTER TAKING THE 20
MG DOSE OF PREDNISONE. HE
REMAINS IN CLOSE CONTACT
WITH HIS
RHEUMATOLOGIST.COVID
TEST 20AUG20- NEGATIVE
PT FELT BETTER W/
PREDNISONE. OFF PREDNISONE
AROUND 4SEP20 W/
RECURRENCE OF AXIAL
MYALGIAS. WENT TO RHEUM
9SEP20. ON 20MG PREDNISONE
FOR 2 WEEKS THEN SLOW
TAPER

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

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

AEID	USA-US078-2021-MRNA-1273-P30 1000011
Adverse event	IDIOPATHIC INTERSTITIAL PNEUMONITIS
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)	28 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	16 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

PRESENTED TO ED WITH 2
WEEKS OF WORSENING
FATIGUE, GENERALIZED
WEAKNESS, DYSPNEA ON
EXERTION,
LIGHTHEADEDNESS,
DECREASED APPETITE, AND 3-4
FALLS OVER THE PAST 3
WEEKS. 2-3 DAYS AGO HAD
DARK TARRY STOOL.
ADMITTED TO HOSPITAL
29JAN2021.

COVID-19 TESTS: 29JAN2021,
01FEB2021, AND 03FEB2021, ALL
NEGATIVE

RELEVANT LAB/DIAGNOSTIC
TESTS- 07FEB21- CHEST CT
INDICATES POSSIBLE
PNEUMONITIS. 29JAN21- LOW
HGB AT ADMISSION (6.9 G/DL)

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

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

AEID	USA-US078-2021-MRNA-1273-P30 1000020
Adverse event	DIPLOPIA
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)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 APR 2021
Hospital Discharge Date (dd MMM yyyy)	07 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT PRESENTED TO HOSPITAL 04APR2021 WITH 5 DAYS OF DIPLOPIA
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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

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

Yes ☒

No ☐

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication STROKE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication STROKE

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

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication BUPROPION

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1980
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication MULTIVITIMIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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 (7)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication BISOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HEART FAILURE/HTN

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUL 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication LEVOTHYRONINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 1.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOW BACK PAIN
WITH INTERMITTENT FLARE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE POLYMYALGIA
RHEUMATICA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	21 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE POLYMYALGIA
RHEUMATICA

Dose per administration 15

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 (11)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		20 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 AUG 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 (12)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication POLYMYALGIA RHEUMATICA

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 (12)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 (13)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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 (14)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication PREMATURE VENTRICULAR
COMPLEX

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication COLASE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 (15)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (16)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (17)

Data signed: (b) (4) 25 Apr 2021 10:56:38

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Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
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 (18)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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 6 HOURS PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	29 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)		16 FEB 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 (19)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

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

EVERY 4 HOURS PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
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 (20)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 4

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 (20)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	29 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)	08 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 12

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 (21)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	30 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)	08 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	29 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)	06 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication METAMUCIL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 1

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

If dose unit is Other, specify PACKET

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 (23)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
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 (24)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication COAGULANT PROPHYLAXIS

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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 (24)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

TWICE DAILY AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 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 (26)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AND FEVER

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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 (27)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication AMINOPHYLLINE

Prophylaxis Yes ☐
No ☒

Indication IDIOPATHIC INTERSTITIAL
PNEUMONITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		31 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)		31 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"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication AFRIN

Prophylaxis Yes ☐
No ☒

Indication IDIOPATHIC INTERSTITIAL
PNEUMONITIS

Dose per administration 0.05

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

If dose unit is Other, specify PERCENT

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 TWICE DAILY AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication WHEEZING ASSOCIATED WITH
IDIOPATHIC INTERSTITIAL
PNEUMONITIS

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

EVERY 4 HOURS PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
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"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication ATOVAQUONE

Prophylaxis Yes ☐
No ☒

Indication PJP PROPHYLAXIS

Dose per administration 750/5

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)		08 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication SOLU-MEDROL

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 24

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PMR

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 25 Apr 2021 10:56:38

Generated On: 09 Jun 2021 17:36:50

	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)	15 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 Apr 2021 20:28:36

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 JAN 2021	CARDIAC ULTRASOUND	Adverse Event	
29 JAN 2021	CHEST XR	Adverse Event	
29 JAN 2021	CT HEAD	Adverse Event	
31 JAN 2021	MYOCARDIAL PERFUSION SPECT STUDY	Adverse Event	
02 FEB 2021	LUNG VENTILATION AND PERFUSION SCAN	Adverse Event	
03 FEB 2021	CT CHEST	Adverse Event	
16 FEB 2021	ABDOMEN ULTRASOUND	Adverse Event	

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

Date of dosing discontinuation (dd MMM yyyy) 26 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #1

US3432023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:50

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 ☐

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/AUG/2020 09:37
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.	True

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/AUG/2020 11:19
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/AUG/2020 10:11
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/AUG/2020 09:43
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/SEP/2020 08:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:43
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/OCT/2020 20:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 15 Feb 2021 23:34:21

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/FEB/2021 15:12
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

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/FEB/2021 21:38
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

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/FEB/2021 11:21
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

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/APR/2021 13:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 11:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000020
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000020
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 14:40
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

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 10:56:39

Generated On: 09 Jun 2021 17:36:50

SAEID	USA-US078-2021-MRNA-1273-P301000020
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/APR/2021 14:57
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

US3432023 (Prod: Brigham and Womens Hospital)

US3432023

Form: Participant Creation

Generated On: 09 Jun 2021 17:36:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'US3432023'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:14:23

US3432023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:14:24

US3432023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[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 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'SCRN'	System	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered (b) (6) 1937'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:14:25

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '83'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'YEARS'	System	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '83'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Male (M)'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'l'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Aug 2020'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2020'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:14:24

US3432023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'l'	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:36:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:58:25

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 22:34:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 22:34:38
Data point term sent to Coder	System	21 Oct 2020 22:33:52
Coding entries removed.	Jun Bai Park Chang	21 Oct 2020 22:33:10
User entered 'AORTIC STENOSIS' reason for change: Per Query Resolution	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Jun Bai Park Chang	21 Oct 2020 22:33:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	06 Aug 2020 07:19:03
User entered 'Aortic stenosis s/p TAVR'	(b) (4)	
	Coder Import (b) (4)	06 Aug 2020 07:19:03
	(b) (4)	
	System	05 Aug 2020 22:59:21
	Monica Feeley (b) (4)	05 Aug 2020 22:59:03
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un Jun 2019'	Monica Feeley (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:15:16
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:15
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:37:32
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jun 2019'	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2019'	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
Data point term sent to Coder	System	05 Aug 2020 23:00:21
User entered 'congestive heart failure'	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN Jun 2019'	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jun 2019'	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2019'	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
Data point term sent to Coder	System	05 Aug 2020 23:00:22
User entered 'mild depression'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 1980'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 1980'	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '1980'	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:04:07
Query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' answered with 'this is not considered an immunosuppressive state. No IS treatment. Pt does not have multiple myeloma ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 21:00:30
User opened query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:37:28
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Plasma cell neoplasms, HLT: Plasma cell neoplasms NEC, PT: Hypergammaglobulinaemia benign monoclonal, LLT: Monoclonal gammopathy of unknown significance - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:46:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:46:27
Data point term sent to Coder	System	05 Aug 2020 23:00:24
User entered 'monoclonal gammopathy of undetermined significance'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2012'	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2012'	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2012'	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Renal failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:48:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:48:13
Data point term sent to Coder	System	05 Aug 2020 23:01:24
User entered 'Mild renal failure'	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un UNK 2013'	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2013'	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2013'	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:41:09
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'etiology unknown' (Site from DM).	Monica Feeley (b) (4)	30 Sep 2020 17:45:02
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:37:46
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
Data point term sent to Coder	System	05 Aug 2020 23:01:25
User entered 'Chronic Anemia'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2012'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2012'	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2012'	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
Data point term sent to Coder	System	05 Aug 2020 23:01:25
User entered 'Stroke'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pneumonia pneumococcal, LLT: Pneumococcal pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Pneumococcal Pneumonia'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2010'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2010'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
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: Penicillin allergy - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:35:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:35:44
Data point term sent to Coder	System	31 Aug 2020 20:12:24
Coding entries removed.	Monica Feeley (b) (4)	31 Aug 2020 20:12:11
User entered 'PENICILLIN ALLERGY (serum sickness)' reason for change: Data Entry Error	Monica Feeley (b) (4)	31 Aug 2020 20:12:11
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: Penicillin allergy - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Penicillin Allergy'	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un UNK 1960'	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 1960'	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '1960'	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Hypothyroidism'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2005'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2005'	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2005'	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
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)	13 Aug 2020 15:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 15:43:37
Data point term sent to Coder	System	11 Aug 2020 17:32:19
User entered 'Chronic low back pain with intermittent flare'	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2000'	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Xhoi Mitre (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2000'	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2000'	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:41:33
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'no reported treatment' (Site from DM).	Monica Feeley (b) (4)	30 Sep 2020 17:48:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:38:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 11:08:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 11:08:49
Data point term sent to Coder	System	31 Aug 2020 20:13:27
Coding entries removed.	Monica Feeley (b) (4)	31 Aug 2020 20:12:37
User entered 'HYPERTENSION (well controlled)' reason for change: Data Entry Error	Monica Feeley (b) (4)	31 Aug 2020 20:12:37
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 21:43:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 21:43:31
Data point term sent to Coder	System	25 Aug 2020 21:42:21

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un UNK 2010'	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2010'	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2010'	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	12 Sep 2020 19:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Sep 2020 19:39:35
Data point term sent to Coder	System	12 Sep 2020 19:38:59
User entered 'Hyperlipidemia'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 1980'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 1980'	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '1980'	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 04:56:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 04:56:40
Data point term sent to Coder	System	12 Sep 2020 19:39:00
User entered 'Premature Ventricular Complex'	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN UNK 2010'	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2010'	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2010'	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
Data point term sent to Coder	System	12 Sep 2020 19:40:00
User entered 'Constipation'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN Jan 2020'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2020'	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2020'	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Cardiac disorders, HLTG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary heart disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
Data point term sent to Coder	System	12 Sep 2020 19:40:00
User entered 'Coronary Heart Disease'	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'UN Nov 2019'	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Nov 2019'	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2019'	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Transcatheter aortic valve implantation, LLT: Transcatheter aortic valve implantation - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 06:46:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 06:46:39
Data point term sent to Coder	System	10 Nov 2020 21:25:48
Coding entries removed.	Monica Feeley (b) (4)	10 Nov 2020 21:25:37
User entered 'TAVR for Aortic Stenosis' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Nov 2020 21:25:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Transcatheter aortic valve implantation, LLT: Transcatheter aortic valve implantation - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 12:06:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 12:06:34
Data point term sent to Coder	System	21 Oct 2020 22:34:52
User entered 's/p TAVR'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'un Jun 2019'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'un Jun 2019'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jun 2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jun 2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:27:40
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'Seasonal allergies'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Un UNK 2010'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'Jan 2010'	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '2010'	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered empty.	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '12:24'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered '5 Aug 2020 12:24'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '171.1' cm	Monica Feeley (b) (4)	05 Aug 2020 22:57:59
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '77.0' kg	Monica Feeley (b) (4)	05 Aug 2020 22:57:59
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
Amendment Manager: User entered '26.30212'	System	16 Sep 2020 23:44:01
User entered '26.3'	System	05 Aug 2020 22:57:59
DataPoint set to visible.	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'kg/m2'	System	05 Aug 2020 22:57:59
DataPoint set to visible.	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '36.9' C	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:19:43
Query 'Data is required. Please provide.' answered with 'no its not' (Site from System).	Jessica Cauley (b) (4)	13 Aug 2020 18:00:26
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:00:20
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered 'Oral (Oral)'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '060'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'bpm'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '015'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'breaths/min'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '160'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'mmHg'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '072'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User entered 'mmHg'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33

US3432023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 22:52:26

US3432023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 03:36:56
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 22:24:14
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 22:52:26
	(b) (4)	

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'l'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:47:33
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '05 Aug 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:35:18
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'VISIT1'	System	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:49:32

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:15:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:15:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 16:49:32
User entered '184652' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:49:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:49:32

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

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)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

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)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Pre-Dose (PREDOSE)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '12:24'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '5 Aug 2020 12:24'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '36.9' C	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Oral (Oral)'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '060'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'bpm'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '015'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'breaths/min'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 13:06:59
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Blood pressure is NCS and pre dose baseline blood pressure so AE not applicable.' (Site from System).	Monica Feeley (b) (4)	06 Aug 2020 12:00:29
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Aug 2020 23:16:10
User entered '160'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '072'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Post-Dose (POSTDOSE)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:39:07
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol fine' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:39:06
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 23:16:10
User entered '14:24'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '5 Aug 2020 14:24'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '36.9' C	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Oral (Oral)'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '061'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'bpm'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '015'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'breaths/min'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '143'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '065'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 22:52:16

US3432023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 22:52:16

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

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)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '13:54'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '5 Aug 2020 13:54'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'ONCE'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '13:00'	Monica Feeley (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '5 Aug 2020 13:00'	System	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '13:05'	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '5 Aug 2020 13:05'	System	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:17:24

US3432023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	05 Aug 2020 23:17:24

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:32:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3' User entered 'Yes (Y)'	System	05 Aug 2020 18:33:39
	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3' User entered '98.4'	System	05 Aug 2020 18:33:39
	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3'	System	05 Aug 2020 18:33:39
User entered 'No (N)'	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3' User entered '05 Aug 2020 14:33'	System	05 Aug 2020 18:33:39
	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:05', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119' User entered 'Yes (Y)'	System	06 Aug 2020 13:11:11
	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119' User entered '98.4'	System	06 Aug 2020 13:11:11
	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119'	System	06 Aug 2020 13:11:11
User entered 'No (N)'	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119' User entered '06 Aug 2020 09:11'	System	06 Aug 2020 13:11:11
	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered 'Yes (Y)'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:44', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '98.6'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered 'Yes (Y)'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:51:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 19:43:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Aug 2020 08:04:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '1'	System	07 Aug 2020 08:04:34
User entered '1'	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '0'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:28', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '07 Aug 2020 04:04'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered 'Yes (Y)'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42' User entered '97.9'	System	08 Aug 2020 12:57:03
	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered 'No (N)'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42' User entered '08 Aug 2020 08:57'	System	08 Aug 2020 12:57:03
	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:42:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered 'Yes (Y)'	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '98.4'	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:41:30', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered 'Yes (Y)'	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:52:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:40:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 19:44:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Aug 2020 10:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:40:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '1'	System	09 Aug 2020 10:43:15
User entered '1'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:40:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '0'	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '09 Aug 2020 06:43'	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:41:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1' User entered 'Yes (Y)'	System	10 Aug 2020 13:42:10
	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:41:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1' User entered '98.4'	System	10 Aug 2020 13:42:10
	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1' User entered 'No (N)'	System	10 Aug 2020 13:42:10
	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:09', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1' User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:42:10
	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebac742fad' User entered 'Yes (Y)'	System	11 Aug 2020 11:07:55
	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:40', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad' User entered '97.6'	System	11 Aug 2020 11:07:55
	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad' User entered 'No (N)'	System	11 Aug 2020 11:07:55
	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:51', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad' User entered '11 Aug 2020 07:07'	System	11 Aug 2020 11:07:55
	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered 'Yes (Y)'	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '97.4'	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered 'Yes (Y)'	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:52:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 19:44:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 13:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '1'	System	12 Aug 2020 13:48:13
User entered '1'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '0'	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:11', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '12 Aug 2020 09:48'	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 8'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 9'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1' User entered 'None (1)'	System	05 Aug 2020 18:34:19
	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:57', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1' User entered 'No (N)'	System	05 Aug 2020 18:34:19
	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1' User entered 'No (N)'	System	05 Aug 2020 18:34:19
	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:10', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1' User entered 'None (1)'	System	05 Aug 2020 18:34:19
	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:17', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1' User entered '05 Aug 2020 14:34'	System	05 Aug 2020 18:34:19
	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'None (1)'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'No (N)'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'No (N)'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'None (1)'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered '06 Aug 2020 09:12'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:40', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0' User entered 'None (1)'	System	07 Aug 2020 08:05:08
	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0' User entered 'No (N)'	System	07 Aug 2020 08:05:08
	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0' User entered 'No (N)'	System	07 Aug 2020 08:05:08
	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0' User entered 'None (1)'	System	07 Aug 2020 08:05:08
	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0' User entered '07 Aug 2020 04:05'	System	07 Aug 2020 08:05:08
	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:10', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635' User entered 'None (1)'	System	08 Aug 2020 12:57:35
	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635' User entered 'No (N)'	System	08 Aug 2020 12:57:35
	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635' User entered 'No (N)'	System	08 Aug 2020 12:57:35
	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635' User entered 'None (1)'	System	08 Aug 2020 12:57:35
	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:31', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635' User entered '08 Aug 2020 08:57'	System	08 Aug 2020 12:57:35
	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f' User entered 'None (1)'	System	09 Aug 2020 10:43:40
	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f' User entered 'No (N)'	System	09 Aug 2020 10:43:40
	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f' User entered 'No (N)'	System	09 Aug 2020 10:43:40
	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:32', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f' User entered 'None (1)'	System	09 Aug 2020 10:43:40
	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f' User entered '09 Aug 2020 06:43'	System	09 Aug 2020 10:43:40
	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ac52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'None (1)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ac52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'No (N)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ac52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'No (N)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ac52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'None (1)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ac52-734a8870c429' User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:42:32
	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'None (1)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:04', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'No (N)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'No (N)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'None (1)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:17', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered '11 Aug 2020 07:08'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f' User entered 'None (1)'	System	12 Aug 2020 13:48:46
	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:28', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f' User entered 'No (N)'	System	12 Aug 2020 13:48:46
	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f' User entered 'No (N)'	System	12 Aug 2020 13:48:46
	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:38', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f' User entered 'None (1)'	System	12 Aug 2020 13:48:46
	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f' User entered '12 Aug 2020 09:48'	System	12 Aug 2020 13:48:46
	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:31', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'None (0)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered 'No (N)'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:51', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d' User entered '05 Aug 2020 14:34'	System	05 Aug 2020 18:34:53
	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered 'None (0)'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:09', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered 'None (0)'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered 'None (0)'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered 'None (0)'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered 'No (N)'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9' User entered '06 Aug 2020 09:13'	System	06 Aug 2020 13:14:00
	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'None (0)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'No interference with activity (1)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'None (0)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'None (0)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'None (0)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:06', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'None (0)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered 'No (N)'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790' User entered '07 Aug 2020 04:06'	System	07 Aug 2020 08:06:21
	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:44', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'None (0)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered 'No (N)'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9' User entered '08 Aug 2020 08:58'	System	08 Aug 2020 12:58:21
	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:54', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:07', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'No (N)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered '09 Aug 2020 06:44'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:42', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'No (N)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'No interference with activity (1)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'None (0)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'None (0)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'None (0)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'None (0)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'None (0)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:09:02', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered 'No (N)'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:09:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411' User entered '11 Aug 2020 07:09'	System	11 Aug 2020 11:09:09
	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:04', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'No (N)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered '12 Aug 2020 09:49'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	11 Aug 2020 11:09:09
User entered 'Day 8'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 9'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

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)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:36:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:02

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	19 Aug 2020 16:13:02

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '19 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:16

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	19 Aug 2020 16:13:16

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:59

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	27 Aug 2020 00:16:59

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '02 Sep 2020'	Bruce Bausk (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'VISIT2'	System	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '02 Sep 2020'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '14:06'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '02 Sep 2020 14:06'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '36.4' C	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '55'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'bpm'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '16'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'breaths/min'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 12:43:32
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Hypertension noted in medical history as pre-existing condition' (Site from System).	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:33:38
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 22:30:50
User entered '174'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '72'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'mmHg'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Sep 2020 22:32:34

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '02 Sep 2020'	Bruce Bausk (b) (4)	02 Sep 2020 22:32:34

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		02 Sep 2020 22:32:10
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	02 Sep 2020 22:32:10
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	02 Sep 2020 22:31:48
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

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)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '02 Sep 2020'	Bruce Bausk (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '13:35'	Bruce Bausk (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '02 Sep 2020 13:35'	System	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '02 Sep 2020'	Bruce Bausk (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '14:07'	Bruce Bausk (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '02 Sep 2020 14:07'	System	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'No (N)'	Bruce Bausk (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Bruce Bausk (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered empty.	System	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	10 Sep 2020 22:30:26

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'I'	System	10 Sep 2020 22:30:26

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:52

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	12 Sep 2020 11:34:52

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '17 Sep 2020'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:31:22

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	23 Sep 2020 15:31:22

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:42:56

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	23 Sep 2020 15:42:56

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Alexander Mills (b) (4)	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '01 Oct 2020'	Alexander Mills (b) (4)	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Clinic (Clinic)'	Alexander Mills (b) (4)	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered 'VISIT3'	System	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '01 Oct 2020'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '15:17'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered '01 Oct 2020 15:17'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '97.6' F	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Oral (Oral)'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty.	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '68'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered 'bpm'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '12'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered 'breaths/min'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '124'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered 'mmHg'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '61'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01
User entered 'mmHg'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:23:01

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	01 Oct 2020 20:18:14
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	01 Oct 2020 20:17:55
User entered 'No (N)'	Alexander Mills (b) (4)	01 Oct 2020 20:17:55

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	01 Oct 2020 20:18:14
User entered '01 Oct 2020'	Alexander Mills (b) (4)	01 Oct 2020 20:17:55

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '01 Oct 2020'	Julia Klopfer (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered '15:44'	Julia Klopfer (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered '01 Oct 2020 15:44'	System	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:35:11
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	01 Oct 2020 20:32:46

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'I'	System	01 Oct 2020 20:32:46

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 64'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 71'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 78'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 92'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:12:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9'	System	06 Nov 2020 20:13:55
User entered 'No (N)'	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:12:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9'	System	06 Nov 2020 20:13:55
User entered 'Yes (Y)'	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:13:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9'	System	06 Nov 2020 20:13:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:13:42', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9' User entered '06 Nov 2020 15:13:42'	System	06 Nov 2020 20:13:55
	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 99'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Please 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)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:27:06
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 106'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:02', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2'	System	16 Nov 2020 18:49:21
User entered 'No (N)'	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2'	System	16 Nov 2020 18:49:21
User entered 'No (N)'	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2' User entered '16 Nov 2020 13:49:18'	System	16 Nov 2020 18:49:21
	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:20:55
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b' User entered 'No (N)'	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b' User entered 'No (N)'	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:34', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b' User entered '22 Nov 2020 10:22:34'	System	22 Nov 2020 15:22:37
	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-29T12:27:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e79bb105-60fb-4e6a-89d3-18f01706ff1f' User entered 'No (N)'	System	29 Nov 2020 17:28:13

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-29T12:28:06', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e79bb105-60fb-4e6a-89d3-18f01706ff1f' User entered 'No (N)'	System	29 Nov 2020 17:28:13

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-29T12:28:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e79bb105-60fb-4e6a-89d3-18f01706ff1f' User entered '29 Nov 2020 12:28:12'	System	29 Nov 2020 17:28:13
	System	29 Nov 2020 17:28:13

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-08T14:37:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e7a8b962-f690-432b-9597-0c54a183692d' User entered 'No (N)'	System	08 Dec 2020 19:37:36
	System	08 Dec 2020 19:37:36

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-08T14:37:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e7a8b962-f690-432b-9597-0c54a183692d' User entered 'No (N)'	System	08 Dec 2020 19:37:36
	System	08 Dec 2020 19:37:36

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-08T14:37:32', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e7a8b962-f690-432b-9597-0c54a183692d' User entered '08 Dec 2020 14:37:32'	System	08 Dec 2020 19:37:36
	System	08 Dec 2020 19:37:36

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-15T14:37:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '01995aa2-ded4-46bc-8466-cf4496f435d2' User entered 'No (N)'	System	15 Dec 2020 19:37:25
	System	15 Dec 2020 19:37:25

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-15T14:37:11', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '01995aa2-ded4-46bc-8466-cf4496f435d2' User entered 'No (N)'	System	15 Dec 2020 19:37:25

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-15T14:37:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '01995aa2-ded4-46bc-8466-cf4496f435d2' User entered '15 Dec 2020 14:37:21'	System	15 Dec 2020 19:37:25
	System	15 Dec 2020 19:37:25

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-22T14:41:50', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b11759db-b712-45b3-9324-57aee592ec64'	System	22 Dec 2020 19:42:06
User entered 'No (N)'	System	22 Dec 2020 19:42:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-22T14:41:54', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b11759db-b712-45b3-9324-57aee592ec64' User entered 'No (N)'	System	22 Dec 2020 19:42:06
	System	22 Dec 2020 19:42:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-22T14:42:02', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b11759db-b712-45b3-9324-57aee592ec64'	System	22 Dec 2020 19:42:06
User entered '22 Dec 2020 14:42:02'	System	22 Dec 2020 19:42:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-29T06:29:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd7209ea4-280f-42e2-9798-344397297ca7' User entered 'No (N)'	System	29 Dec 2020 11:29:16
	System	29 Dec 2020 11:29:16

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-29T06:29:05', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd7209ea4-280f-42e2-9798-344397297ca7' User entered 'No (N)'	System	29 Dec 2020 11:29:16
	System	29 Dec 2020 11:29:16

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-12-29T06:29:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd7209ea4-280f-42e2-9798-344397297ca7' User entered '29 Dec 2020 06:29:13'	System	29 Dec 2020 11:29:16
	System	29 Dec 2020 11:29:16

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-04T14:15:38', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '699cfe17-c11d-41c9-a832-4fc1a1912ba9' User entered 'No (N)'	System	04 Jan 2021 19:15:53
	System	04 Jan 2021 19:15:53

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-04T14:15:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '699cfe17-c11d-41c9-a832-4fc1a1912ba9' User entered 'No (N)'	System	04 Jan 2021 19:15:53

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-04T14:15:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '699cfe17-c11d-41c9-a832-4fc1a1912ba9' User entered '04 Jan 2021 14:15:49'	System	04 Jan 2021 19:15:53
	System	04 Jan 2021 19:15:53

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-11T17:59:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9516b289-a15c-46bb-8919-83dba1e46129' User entered 'No (N)'	System	11 Jan 2021 23:00:06
	System	11 Jan 2021 23:00:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-11T17:59:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9516b289-a15c-46bb-8919-83dba1e46129' User entered 'No (N)'	System	11 Jan 2021 23:00:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-11T18:00:04', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9516b289-a15c-46bb-8919-83dba1e46129' User entered '11 Jan 2021 18:00:04'	System	11 Jan 2021 23:00:06
	System	11 Jan 2021 23:00:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-19T15:01:24', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fa632f6a-aa46-4923-a802-b04ec4cb0339'	System	19 Jan 2021 20:01:41
User entered 'No (N)'	System	19 Jan 2021 20:01:41

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-19T15:01:28', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fa632f6a-aa46-4923-a802-b04ec4cb0339'	System	19 Jan 2021 20:01:41
User entered 'No (N)'	System	19 Jan 2021 20:01:41

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-19T15:01:34', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fa632f6a-aa46-4923-a802-b04ec4cb0339' User entered '19 Jan 2021 15:01:34'	System	19 Jan 2021 20:01:41
	System	19 Jan 2021 20:01:41

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-24T15:02:44', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3a192db-f83e-409d-ac6c-ac81873233f9'	System	24 Jan 2021 20:02:59
User entered 'No (N)'	System	24 Jan 2021 20:02:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-24T15:02:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3a192db-f83e-409d-ac6c-ac81873233f9' User entered 'No (N)'	System	24 Jan 2021 20:02:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-01-24T15:02:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3a192db-f83e-409d-ac6c-ac81873233f9' User entered '24 Jan 2021 15:02:55'	System	24 Jan 2021 20:02:59
	System	24 Jan 2021 20:02:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:02:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb' User entered 'Yes (Y)'	System	02 Feb 2021 17:09:54
	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:03:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb' User entered 'No (N)'	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:03:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb' User entered 'No (N)'	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:03:50', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb' User entered 'Yes (Y)'	System	02 Feb 2021 17:09:54
	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:04:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb'	System	02 Feb 2021 17:09:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-02T12:04:32', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '0f5115d6-24fd-4063-9e21-f9eaf944faeb' User entered '02 Feb 2021 12:04:32'	System	02 Feb 2021 17:09:54
	System	02 Feb 2021 17:09:54

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-12T03:41:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '462a5c93-8406-45ad-869e-74ed8b5b8170'	System	12 Feb 2021 08:43:20
User entered 'Yes (Y)'	System	12 Feb 2021 08:43:20

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-12T03:42:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '462a5c93-8406-45ad-869e-74ed8b5b8170'	System	12 Feb 2021 08:43:20
User entered 'No (N)'	System	12 Feb 2021 08:43:20

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-12T03:42:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '462a5c93-8406-45ad-869e-74ed8b5b8170'	System	12 Feb 2021 08:43:20
User entered 'No (N)'	System	12 Feb 2021 08:43:20

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-12T03:42:54', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '462a5c93-8406-45ad-869e-74ed8b5b8170'	System	12 Feb 2021 08:43:20
User entered 'No (N)'	System	12 Feb 2021 08:43:20

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-12T03:43:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '462a5c93-8406-45ad-869e-74ed8b5b8170'	System	12 Feb 2021 08:43:20
User entered '12 Feb 2021 03:43:14'	System	12 Feb 2021 08:43:20

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:49:35-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5'	System	03 Mar 2021 00:59:35
User entered 'Yes (Y)'	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:49:43-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5'	System	03 Mar 2021 00:59:35
User entered 'No (N)'	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:49:50-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5'	System	03 Mar 2021 00:59:35
User entered 'No (N)'	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:50:01-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5' User entered 'Yes (Y)'	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:50:39-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5'	System	03 Mar 2021 00:59:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:50:52-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '47ce470d-00dd-41cc-9ea4-f0106d703cb5' User entered '28 Feb 2021 17:50:52'	System	03 Mar 2021 00:59:35
	System	03 Mar 2021 00:59:35

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-14T16:04:58-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '6b254955-d935-4403-a4b6-747499827150'	System	14 Mar 2021 20:05:22
User entered 'No (N)'	System	14 Mar 2021 20:05:22

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-14T16:05:06-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '6b254955-d935-4403-a4b6-747499827150'	System	14 Mar 2021 20:05:22
User entered 'No (N)'	System	14 Mar 2021 20:05:22

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-14T16:05:17-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '6b254955-d935-4403-a4b6-747499827150'	System	14 Mar 2021 20:05:22
User entered '14 Mar 2021 16:05:17'	System	14 Mar 2021 20:05:22

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-19T15:33:51-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8fee1442-161f-4759-852f-04478b41885a'	System	19 Mar 2021 19:34:10
User entered 'No (N)'	System	19 Mar 2021 19:34:10

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-19T15:33:55-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8fee1442-161f-4759-852f-04478b41885a'	System	19 Mar 2021 19:34:10
User entered 'No (N)'	System	19 Mar 2021 19:34:10

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-19T15:34:05-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8fee1442-161f-4759-852f-04478b41885a' User entered '19 Mar 2021 15:34:05'	System	19 Mar 2021 19:34:10
	System	19 Mar 2021 19:34:10

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-29T21:37:48-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'a87ddb7e-13b4-491d-bb4b-747c19bfa268'	System	30 Mar 2021 01:41:38
User entered 'No (N)'	System	30 Mar 2021 01:41:38

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-29T21:37:54-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'a87ddb7e-13b4-491d-bb4b-747c19bfa268'	System	30 Mar 2021 01:41:38
User entered 'No (N)'	System	30 Mar 2021 01:41:38

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-03-29T21:38:03-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'a87ddb7e-13b4-491d-bb4b-747c19bfa268' User entered '29 Mar 2021 21:38:03'	System	30 Mar 2021 01:41:38

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T12:34:56-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'Yes (Y)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:42:42-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'Yes (Y)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:43:12-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:43:19-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'No (N)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:43:33-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'Yes (Y)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:43:38-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-04-06T13:43:45-04:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'd644c63c-6f87-495d-9c43-73eafbbc21b5'	System	06 Apr 2021 17:43:59
User entered '06 Apr 2021 13:43:45'	System	06 Apr 2021 17:43:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:50

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)	26 Apr 2021 09:44:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:51:56-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'cecb47a4-95a9-4dd8-928d-7b14d4023254'	System	11 Mar 2021 20:50:05
User entered 'No (N)'	System	11 Mar 2021 20:50:05

US3432023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:44:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2021-02-28T12:52:03-05:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'cecb47a4-95a9-4dd8-928d-7b14d4023254' User entered '28 Feb 2021 17:52:03'	System	11 Mar 2021 20:50:05
	System	11 Mar 2021 20:50:05

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:40:50

US3432023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:22:40
User entered 'l'	System	30 Nov 2020 20:40:50

US3432023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:42:01

US3432023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:42:01

US3432023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Nov 2020 20:42:01

US3432023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:42:01

US3432023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:42:07

US3432023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered 'l'	System	30 Nov 2020 20:42:07

US3432023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 21:46:00

US3432023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '29 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 21:46:00

US3432023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 21:46:00

US3432023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 21:46:00

US3432023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 21:46:04

US3432023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered 'l'	System	29 Dec 2020 21:46:04

US3432023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:22:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	31 Mar 2021 21:27:52
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:01:19
User entered empty; reason for change Data Entry Error	(b) (4)	31 Mar 2021 16:01:07
User entered 'Yes (Y)'	System	31 Mar 2021 16:01:07
	Megan Powell (b) (4)	31 Mar 2021 16:01:07
	(b) (4)	
	Megan Powell (b) (4)	31 Mar 2021 15:54:22
	(b) (4)	

US3432023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '27 Jan 2021' reason for change: Data Entry Error	Julia Klopfer (b) (4)	31 Mar 2021 21:27:52
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:01:07
User entered '27 Jan 2021'	Megan Powell (b) (4)	31 Mar 2021 15:54:22

US3432023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	31 Mar 2021 21:27:52
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:01:07
User entered 'Contact Made (CONTACT MADE)'	Megan Powell (b) (4)	31 Mar 2021 15:54:22

US3432023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Participant unable to speak with research team as he was in the hospital at the time of the call' reason for change: Data Entry Error	Julia Klopfer (b) (4)	31 Mar 2021 21:27:52
User entered empty.	Megan Powell (b) (4)	31 Mar 2021 15:54:22

US3432023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:22:18
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:01:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Mar 2021 16:01:23
User entered empty; reason for change Data Entry Error	System	31 Mar 2021 16:01:23
User entered 'Yes (Y)'	Megan Powell (b) (4)	31 Mar 2021 16:01:23
	(b) (4)	
	Megan Powell (b) (4)	31 Mar 2021 15:54:29
	(b) (4)	

US3432023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:01:23
User entered 'l'	System	31 Mar 2021 15:54:29

US3432023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:21:33
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:48
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:01:53
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 16:01:44
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:01:44
User entered 'Yes (Y)'	Megan Powell (b) (4)	31 Mar 2021 15:56:43

US3432023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:01:44
User entered '24 Feb 2021'	Megan Powell (b) (4)	31 Mar 2021 15:56:43

US3432023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:01:44
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	31 Mar 2021 15:56:43

US3432023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered 'VISIT4'	System	31 Mar 2021 22:28:48
User entered empty.	System	31 Mar 2021 16:01:44
User entered 'VISIT4'	System	31 Mar 2021 15:56:43

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:21:37
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:29:01
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:02:35
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 16:02:26
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered 'Yes (Y)'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '24 Feb 2021'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '14:07'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:02:26
User entered '24 Feb 2021 14:07'	System	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '98.1' F	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered 'Oral (Oral)'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '090'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:02:26
User entered 'bpm'	System	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '016'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:02:26
User entered 'breaths/min'	System	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '133'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:02:26
User entered 'mmHg'	System	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:26
User entered '074'	Megan Powell (b) (4)	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:02:26
User entered 'mmHg'	System	31 Mar 2021 15:57:19

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48

US3432023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48

US3432023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:21:41
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:29:12
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:02:45
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 16:02:39
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:02:39
User entered 'No (N)'	Megan Powell (b) (4)	31 Mar 2021 15:57:26

US3432023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Megan Powell (b) (4)	31 Mar 2021 15:57:26

US3432023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:21:44
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:29:16
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:03:19
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 16:03:04
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:03:04
User entered 'Yes (Y)'	Megan Powell (b) (4)	31 Mar 2021 15:57:44

US3432023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:03:04
User entered '24 Feb 2021'	Megan Powell (b) (4)	31 Mar 2021 15:57:44

US3432023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:03:04
User entered '14:20'	Megan Powell (b) (4)	31 Mar 2021 15:57:44

US3432023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered empty.	System	31 Mar 2021 16:03:04
User entered '24 Feb 2021 14:20'	System	31 Mar 2021 15:57:44

US3432023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:21:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:29:23
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Megan Powell (b) (4)	31 Mar 2021 16:03:33
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 16:03:25
User entered empty; reason for change Data Entry Error	Megan Powell (b) (4)	31 Mar 2021 16:03:25
User entered 'Yes (Y)'	Megan Powell (b) (4)	31 Mar 2021 15:59:17

US3432023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:10:48
User entered '1'	System	31 Mar 2021 22:29:23
User entered empty.	System	31 Mar 2021 16:03:25
User entered '1'	System	31 Mar 2021 15:59:17

US3432023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	02 Apr 2021 14:31:21

US3432023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '2 Apr 2021'	Tenaizus Woods (b) (4)	02 Apr 2021 14:31:21

US3432023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	02 Apr 2021 14:31:21

US3432023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Tenaizus Woods (b) (4)	02 Apr 2021 14:31:21

US3432023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	02 Apr 2021 14:31:35

US3432023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:59
User entered 'l'	System	02 Apr 2021 14:31:35

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:14
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Monica Feeley (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:14
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11:00'	Monica Feeley (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:14
User entered '7 Aug 2020 11:00'	System	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:14
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Monica Feeley (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:14
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Monica Feeley (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 1 (Day 1)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '99'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '37.0' C	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Mild (Mild)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 2 (Day 2)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8 Aug 2020'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '99'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 14:18:48
Query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	19 Aug 2020 19:21:31
User entered '98.4' F reason for change: Per Query Resolution	Monica Feeley (b) (4)	19 Aug 2020 19:21:24
User opened query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 09:10:13
User entered '98.4' C	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Mild (Mild)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 3 (Day 3)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '9 Aug 2020'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '99'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '98.6' F	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Mild (Mild)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 4 (Day 4)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '10 Aug 2020'	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'l'	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered empty.	System	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 5 (Day 5)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '98'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '98.2' F	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 6 (Day 6)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '12 Aug 2020'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '98'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Day 1 (Day 1)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '6 Aug 2020'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
User entered '%'	System	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Mild (Mild)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:36:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:39:58
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'None (None)'	Monica Feeley (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:45:36
Query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' answered with 'Updated' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:50:55
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:24:33
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:32:30
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:51:06
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:18:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Monica Feeley (b) (4)	16 Sep 2020 21:26:23
Amendment Manager inserted this DataPoint.	(b) (4) System	21 Aug 2020 02:15:11

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	16 Sep 2020 21:26:23
User entered 'Yes (Y)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:36:50

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:11:22
Amendment Manager: User entered '0'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 3 (Day 3)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '09 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 5 (Day 5)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 7 (Day 7)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 9 (Day 9)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 14 (Day 14)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 21 (Day 21)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:36:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User accepted default value 'Day 28 (Day 28)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:36:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered 'SICKD1'	System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User closed query 'Per CDM: Vital signs is performed on 07 Aug 2020 for Unscheduled_7 AUG 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 13:08:12
Query 'Per CDM: Vital signs is performed on 07 Aug 2020 for Unscheduled_7 AUG 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' answered with 'unscheduled visit inactivated' (Site from DM).	Xhoi Mitre (b) (4) (b) (4)	05 Mar 2021 18:49:01
User opened query 'Per CDM: Vital signs is performed on 07 Aug 2020 for Unscheduled_7 AUG 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:48:02
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11:47'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered '7 Aug 2020 11:47'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Jun Bai Park Chang	10 Nov 2020 21:55:38
DataPoint set to visible.	(b) (4) System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Jun Bai Park Chang	10 Nov 2020 21:55:38
DataPoint set to visible.	(b) (4) System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '37' C	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '58'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered 'bpm'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered 'breaths/min'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '138'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered 'mmHg'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '63'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User entered 'mmHg'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:53

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:53

US3432023

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:36:50

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:56:12

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Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:36:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:53
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:56:12

US3432023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	16 Jan 2021 18:42:22

US3432023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:42:22

US3432023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:42:22

US3432023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 18:42:22

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[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 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	26 Mar 2021 16:04:18
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 02:24:09

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Jan 2021 12:56:17
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'Participant did not receive dose 2' (Site from System).	Julia Klopfer (b) (4)	16 Jan 2021 18:43:38
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	16 Jan 2021 18:43:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 18:18:05
Query 'please complete' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	26 Mar 2021 16:04:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	Monica Feeley (b) (4)	26 Mar 2021 16:04:18
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:28:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:24:09

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Placebo (Placebo)'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:13:53
User entered 'Placebo (Placebo)'	Julia Klopfer (b) (4)	16 Jan 2021 18:43:19
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	21 Jan 2021 16:44:44
User entered empty.	Julia Klopfer (b) (4)	16 Jan 2021 18:43:19

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'I'	System	21 Jan 2021 16:44:44
User entered empty.	System	16 Jan 2021 18:43:19

US3432023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'I'	System	21 Jan 2021 16:44:44
User entered empty.	System	16 Jan 2021 18:43:19

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered empty.	System	21 Jan 2021 16:50:12
DataPoint set to visible.	System	21 Jan 2021 16:44:44

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered empty.	System	21 Jan 2021 16:50:12
DataPoint set to visible.	System	21 Jan 2021 16:44:44

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '10:30'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered '16 Jan 2021 10:30'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '37.7' C	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '98'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'bpm'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'breaths/min'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '136'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'mmHg'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '63'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'mmHg'	System	21 Jan 2021 16:50:12

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered empty.	System	21 Jan 2021 16:50:12
DataPoint set to visible.	System	21 Jan 2021 16:44:44

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11:25'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered '16 Jan 2021 11:25'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '99.1' F	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '73'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'bpm'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16'	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'breaths/min'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '136'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'mmHg'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '61'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:12

US3432023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'mmHg'	System	21 Jan 2021 16:50:12

US3432023

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:25

US3432023

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:25

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Julia Klopfer (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered empty.	Julia Klopfer (b) (4) (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'mRNA-1273'	System	21 Jan 2021 16:50:52
DataPoint set to visible.	System	21 Jan 2021 16:44:44

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '10:55'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered '16 Jan 2021 10:55'	System	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Left Arm (LEFT ARM)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'ONCE'	System	21 Jan 2021 16:50:52

US3432023

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

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 16:50:52

US3432023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	16 Jan 2021 18:44:17

US3432023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:44:17

US3432023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '10:30'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:44:17

US3432023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered '16 Jan 2021 10:30'	System	16 Jan 2021 18:44:17

US3432023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:44:35

US3432023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '16 Jan 2021'	Julia Klopfer (b) (4)	16 Jan 2021 18:44:35

US3432023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '10:40'	Julia Klopfer (b) (4) (b) (4)	16 Jan 2021 18:44:35

US3432023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:50

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered '16 Jan 2021 10:40'	System	16 Jan 2021 18:44:35

US3432023

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

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Jan 2021 16:50:56

US3432023

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

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:32:28
User entered 'I'	System	21 Jan 2021 16:50:56

US3432023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	31 Mar 2021 21:19:05

US3432023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '25 Jan 2021'	Julia Klopfer (b) (4) (b) (4)	31 Mar 2021 21:19:05

US3432023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4) (b) (4)	31 Mar 2021 21:19:05

US3432023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Julia Klopfer (b) (4)	31 Mar 2021 21:19:05

US3432023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 20:47:29

US3432023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User entered 'l'	System	31 Mar 2021 20:47:29

US3432023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User entered 'I'	System	31 Mar 2021 20:47:29
DataPoint set to visible.	System	31 Mar 2021 20:47:29

US3432023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:08

US3432023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:08

US3432023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:08

US3432023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	31 Mar 2021 22:23:08

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:14

US3432023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:19

US3432023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:19

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		31 Mar 2021 22:23:45
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:45
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	31 Mar 2021 22:23:23
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Pt could not come in, contacting pt to see when pt could come in.' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:24:53
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:23
DataPoint set to visible.	System	31 Mar 2021 20:47:29

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:23

US3432023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:23:23

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:26:36
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:23:27

US3432023

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Mar 2021 22:26:36
User entered empty.	System	31 Mar 2021 22:23:27

US3432023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:14

US3432023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:14

US3432023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:14

US3432023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:14

US3432023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 22:28:18

US3432023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Mar 2021 22:28:18

US3432023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 22:28:50
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:28:50
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:28:50
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 22:28:50

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:00

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:00

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:00

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:00

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:00
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:00

US3432023

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 22:29:04
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:04
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 22:29:06
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:06
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 22:29:06
	(b) (4)	

US3432023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 22:29:06

US3432023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:36:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:51
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 14:21:23
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Aug 2020 21:30:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:02:54
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:36:30
User entered 'USA-US078-2020-mRNA-1273-P301000001'	System	21 Aug 2020 13:36:22
User entered 'New'	(b) (4), (b) (6)	21 Aug 2020 13:36:22

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:38
User closed query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:30
Query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' answered with 'this is the underlying diagnosis as of now' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:03:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Polymyalgia rheumatica, LLT: Polymyalgia rheumatica - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 10:55:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 10:55:58
User opened query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:34
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:33:02
Data point term sent to Coder	System	26 Aug 2020 21:32:01
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:31:16
User entered 'Possible Polymyalgia rheumatica' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:31:16
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' answered with 'etiology still unknown, event term staying as weakness for now' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:38:14
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 21:41:23
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 21:41:03
User entered 'Weakness'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:02:59
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:02
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:04
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 21:17:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 21:17:31
User entered 'No (N)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 21:17:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 13:36:22
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:36:22
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:05
User entered '20 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:46
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:48
User closed query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:29:59
Query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' answered with 'condition ongoing' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:37:00
User opened query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:38:08
Query 'Per ETRTR: Please confirm an update reponse if applicable, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:37:39
User opened query 'Per ETRTR: Please confirm an update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:37:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 10:27:56
User closed query 'PV Query: Please provide the event end date. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 10:27:56
Query 'PV Query: Please provide the event end date. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'AE is still ongoing' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 20:39:56
User opened query 'PV Query: Please provide the event end date. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:42

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'not available, not likely to resolve' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:42:39
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety). User closed query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not available yet' (Site from Safety). User opened query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety). User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety). User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Monica Feeley (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Monica Feeley (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 14:28:34 19 Oct 2020 13:06:44 28 Sep 2020 13:27:48 24 Sep 2020 17:36:17 23 Sep 2020 22:17:17 22 Sep 2020 20:51:47 22 Sep 2020 20:51:00 22 Sep 2020 20:50:58 17 Sep 2020 12:33:34

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not available yet' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:03:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:04
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:06:49
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:41:28
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'condition ongoing' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:37:06
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:23
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:41
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:43
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 12:16:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'has not been discharged' (Site from System).	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:41:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Aug 2020 21:40:52
User entered 'I'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:46
User entered '20 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:06
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:52
User closed query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:33:24
Query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' answered with 'updated response' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:22:21
Query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' answered with 'updated with hospital discharge date' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:22:08
User entered '21 Aug 2020' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:21:37
User opened query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:18
User opened query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:38:26
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:54
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:55
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:57
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:59
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:20:01
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:20:03
User entered 'Related (RELATED)' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:31:16
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:08
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 04:39:13
Query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 22:15:24
User opened query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:17:44
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:17:44
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'It is unclear what this query is asking. Per protocol, participant cannot receive further dosing of product. Therefore, we terminated his treatment and he did not receive second dose. The most appropriate choice for "action taken with investigational product" is "investigational product withdrawn," which is reflected here.' (Site from DM).	Monica Feeley (b) (4) (b) (4)	23 Sep 2020 20:42:32
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:53:00
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:34:10
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:14
User entered '0' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:32:53
User entered '1'	(b) (4) Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:17
User entered '1' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:32:53
User entered '0'	(b) (4) Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:19
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until a final diagnosis and plan for long-term treatment and follow-up for the event has been established.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:26
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:16:20
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not available, not like to resolve' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:28:22
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:53:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:42

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not sure if any resolution. Will update information if there is an outcome?' (Site from Safety). DataPoint Verified.	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:06:36
	(b) (4), (b) (6)	04 Sep 2020 15:21:21
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	27 Aug 2020 13:33:07
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:14
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	21 Aug 2020 22:24:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:24:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:25
User entered empty; reason for change New Information	Monica Feeley (b) (4)	27 Aug 2020 13:33:07
User entered 'N/A' reason for change: New Information	Monica Feeley (b) (4)	21 Aug 2020 22:24:07
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:01:52
Query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' answered with 'subject did not receive any vaccines for 6 months prior to study entry ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:40:58
User opened query 'PV Query: Please provide office visit notes and laboratory results from subject's follow-up visits with Rheumatology to Safety_Moderna@iqvia.com when available. Please leave query open/unanswered until able to obtain and send records.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:35:14
User opened query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:56
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:07:00
User closed query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant's symptoms to study vaccination and justification for the relatedness?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:36
User closed query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis "possible PMR" or "PMR"? (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:35
User closed query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx's of PMR)? (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:31
User closed query 'PV Query: The 10-Aug chest CT shows "near complete resolution" of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant's diagnosis the time of this previous chest CT' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:29

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Audit	User	Time (GMT)
User closed query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- "back pain and possibly myalgias might have been noted" -- if these symptoms were documented in the study site records/medical records, state that they were documented]' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:27
User closed query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:25
User closed query 'PV Query: What is the status of the participant's MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:24
User closed query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:22
User closed query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:20
Query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant's symptoms to study vaccination and justification for the relatedness?' answered with 'Rheum discusses possible PMR may be related to vaccine. Will send redacted note' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 22:13:12

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Audit	User	Time (GMT)
Query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- "back pain and possibly myalgias might have been noted" -- if these symptoms were documented in the study site records/medical records, state that they were documented]' answered with 'Medical history obtained at screening visit noted: chronic lower back pain with intermittent flare. Note in binder from 26UAG2020 states: at time of enrollment, pt felt well. However, in retrospect, pt thinks they may have had back pain few days before IP. Mild and though related to chronic back pain' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:12:16
Query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' answered with 'no vaccines noted in medical record. We will have to follow up with participant to confirm' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:07:23
Query 'PV Query: Please provide further details of the clinical course to resolution.' answered with 'Participant currently tapering prednisone. Patient currently on 15 mg prednisone daily. Participant reports they feel good. However, condition has not ended. Participant following up with Rheum for speed of taper as well as overall condition.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:05:31
Query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' answered with 'Medical record states "unspecified type" of hypothyroidism' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:16:36
Query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis "possible PMR" or "PMR"? answered with 'in the consultation notes, it is possible PMR.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:14:38

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Audit	User	Time (GMT)
Query 'PV Query: The 10-Aug chest CT shows “near complete resolution” of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant’s diagnosis the time of this previous chest CT' answered with 'Previous date of CT: 07MAY2019. Diagnosis at time was pulmonary edema because of aortic stenosis. ' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:13:29
Query 'PV Query: What is the status of the participant’s MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' answered with 'Pt saw heme/onc many years ago. Was told no follow up necessary. no notes available from appointment. Currently followed by internist. Last immunofixation 17APR2020 showed no monoclonal band.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:06:49
Query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx of PMR)?' answered with 'Participant has history of pulmonary nodules. This was a follow up exam/CT for monitoring the nodules. ' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 19:19:10
User opened query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant’s symptoms to study vaccination and justification for the relatedness?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:30
User opened query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis “possible PMR” or “PMR”? ' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:19
User opened query 'PV Query: The 10-Aug chest CT shows “near complete resolution” of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant’s diagnosis the time of this previous chest CT' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:03

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Audit	User	Time (GMT)
User opened query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx's of PMR)?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:47
User opened query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- "back pain and possibly myalgias might have been noted" -- if these symptoms were documented in the study site records/medical records, state that they were documented]' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:28
User opened query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:14
User opened query 'PV Query: What is the status of the participant's MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:02
User opened query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:44:51
User opened query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:28:14
Query 'Please provide further details of the clinical course to resolution. Please keep query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:28:07
User closed query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:38:06
User closed query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:38:03

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:59:05
Query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' answered with 'After his discharge summary was received by our site, a study physician called participant to discuss additional medical history and concomitant medications that were found in his record. We rely on participant's verbal medical history and concomitant medications. It is our best practice to trust the participant. Per the conversation the physician had with the participant, all medical history and medication relayed by the participant has been recorded and we updated the source docs and eCRFs. Anything not recorded has been omitted by the participant's verbal communication with us. Physician followed up on all items and participant confirmed the items listed and denied the items not listed.' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	23 Sep 2020 20:48:00
Query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'prednisone is recorded in the proper eCRFs (see concomitant medications)' (Site from DM).	Monica Feeley (b) (4) (b) (4)	23 Sep 2020 20:38:49
Query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' answered with 'he went to rheum on 09SEP2020. He started on 11SEP2020 per CM eCRF' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	23 Sep 2020 20:38:04
User opened query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:52:32

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Audit	User	Time (GMT)
User opened query 'Please provide further details of the clinical course to resolution. Please keep query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:52:28
User opened query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:50:06
User opened query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:49:31
Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:44
User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:42
Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:34
User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:33
User closed query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:57
User closed query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:52
User closed query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:49
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:45

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Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED RHEUMATOLOGY ATTENDING CONSULTATION NOTE WHO SAW PT 21AUG20 AT HOSPITAL. SPOKE W/ RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING IP. SYMPTOMS AT THAT TIME WERE MILD & THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED IP ON 5AUG20 & REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS & PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) & WEAKNESS. DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE 20AUG20, & HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. FELT MUCH BETTER 21AUG20 & DISCHARGED W/ PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME RHEUMATOLOGIST THINKS PMR MAY BE POSSIBLE DIAGNOSIS. BACK PAIN PRESENT BEFORE THE IP ADMINISTRATION, BUT POLYMYALGIA AND WEAKNESS DEVELOPED AFTER VACCINE ADMINISTRATION. WE ARE UPDATING AE TO INCLUDE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING RHEUMATOLOGIST, & TIMING OF DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT VACCINE MAY HAVE	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:38:06

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Audit	User	Time (GMT)
CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST.COVID TEST 20AUG20-NEGATIVE Pt felt better w/ prednisone. Off prednisone around 4SEP20 w/ recurrence of axial myalgias. Went to rheum 9SEP20. On 20mg prednisone for 2 weeks then slow taper' reason for change: New Information Query 'PV Query: Please provide further details of the clinical course to resolution.' answered with 'we will provide updates for management' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:19:51

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Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED CONSULTATION NOTE OF RHEUMATOLOGY ATTENDING WHO SAW PT 21AUG20 AT FAULKNER HOSPITAL. WE SPOKE WITH RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED THAT HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING THE IP. THE SYMPTOMS AT THAT TIME WERE MILD AND THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED THE IP ON 5AUG20 AND REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS AND HE PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) AND WEAKNESS. HE DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE ON 20AUG20, AND HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. FELT MUCH BETTER ON 21AUG20 AND DISCHARGED WITH PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME RHEUMATOLOGIST THINKS PMR MAY BE POSSIBLE DIAGNOSIS. BACK PAIN WAS PRESENT BEFORE THE IP ADMINISTRATION, BUT POLYMYALGIA AND WEAKNESS DEVELOPED AFTER VACCINE ADMINISTRATION. WE ARE UPDATING ADVERSE EVENT TO INCLUDE THESE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING	Monica Feeley (b) (4)	16 Sep 2020 21:18:49

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Audit	User	Time (GMT)
RHEUMATOLOGIST, AND THE TIMING OF THE DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT THE VACCINE MAY HAVE CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST. WE CONTINUE TO FOLLOW PT CLOSELY. COVID test 20AUG2020- negative' reason for change: New Information		
Query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' answered with 'tested at hospital 20AUG2020. negative. ' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:14:01
Query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' answered with 'date, units and reference ranges updated.)CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15).' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:12:47
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Sep 2020 21:11:50

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Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED CONSULTATION NOTE OF RHEUMATOLOGY ATTENDING WHO SAW PT 21AUG20 AT FAULKNER HOSPITAL. WE SPOKE WITH RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED THAT HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING THE IP. THE SYMPTOMS AT THAT TIME WERE MILD AND THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED THE IP ON 5AUG20 AND REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS AND HE PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) AND WEAKNESS. HE DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE ON 20AUG20, AND HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 mg/L (ref 0.0-5.0) AND ESR AT 56 mm/h (ref 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. HE FELT MUCH BETTER ON 21AUG20 AND WAS DISCHARGED WITH A PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME THE RHEUMATOLOGIST THINKS THAT PMR MAY BE A POSSIBLE DIAGNOSIS. BACK PAIN WAS PRESENT BEFORE THE IP ADMINISTRATION, BUT THE POLYMYALGIA AND THE WEAKNESS DEVELOPED AFTER THE VACCINE ADMINISTRATION. WE ARE UPDATING THIS ADVERSE EVENT TO INCLUDE THESE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING	Monica Feeley (b) (4)	16 Sep 2020 21:11:50

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Audit	User	Time (GMT)
RHEUMATOLOGIST, AND THE TIMING OF THE DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT THE VACCINE MAY HAVE CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST. WE CONTINUE TO FOLLOW PT CLOSELY.'		
reason for change: New Information Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' answered with 'provided on epip' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:03:52
User closed query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:34
User closed query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:24
User opened query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 19:58:43
	(b) (4), (b) (6)	04 Sep 2020 15:21:32
User opened query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:22:13
User opened query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:22:02

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:54
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:41:16
User closed query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:36:37
User closed query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:36:25
User closed query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:35:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:35:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'treatment indicated in narrative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:46:06

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Audit	User	Time (GMT)
Query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' answered with 'added additional information about the quality of the weakness' (Site from Safety).	Monica Feeley (b) (4)	26 Aug 2020 21:45:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'relevant laboratory results added to discussion' (Site from Safety).	Monica Feeley (b) (4)	26 Aug 2020 21:45:33
Query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' answered with 'treated added in discussion. added to con meds.' (Site from CRA).	Monica Feeley (b) (4)	26 Aug 2020 21:45:02

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '24AUG20, we received the consultation note of the rheumatology attending who saw pt 21AUG20 at Faulkner Hospital. We spoke with the rheumatologist to discuss the case in detail. At the time of enrollment pt felt well. However, pt noted that he may have started to have back pain a few days before receiving the IP. The symptoms at that time were mild and thought to be related to his chronic back pain. He received the IP on 5AUG20 and reported increased back pain over the next days and he progressively developed migratory myalgias (back, shoulders, occiput, paraspinal muscles) and weakness. He denied any local injection site reaction after vaccination. The myalgias became severe on 20AUG20, and he was not able to get of out bed because of generalized weakness. He was hospitalized between 20AUG20 and 21AUG20. Work-up was notable for CRP at 96.9 and ESR at 56. He received 15 mg of prednisone on 20AUG20. He felt much better on 21AUG20 and was discharged with a prescription of prednisone 20 mg daily, with a planned tapering over 16 days. At this time the rheumatologist thinks that PMR may be a possible diagnosis. Back pain was present before the IP administration, but the polymyalgia and the weakness developed after the vaccine administration. We are updating this adverse event to include these additional symptoms. Given this additional information, the consultation with the treating rheumatologist, and the timing of the development of these symptoms it is possible that the vaccine may have contributed to the symptoms. Thus, we are changing our assessment that there may be a possible relationship between the symptomatology of pt and the study product. As of today's conversation with pt, he feels good during the day, but wakes up in the morning with some pain in the shoulders and neck. The pain goes away approximately 2 hours after taking the 20 mg dose of prednisone. He remains in close contact with his rheumatologist. We continue to follow pt closely.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:44:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' answered with 'there are no risk factors or triggers that may have caused or worsened preexisting' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:37:44
Query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' answered with 'updated to include date' (Site from CRA).	Monica Feeley (b) (4)	25 Aug 2020 21:29:32
User entered 'ADMITEED TO FAULKNER HOSPITAL TODAY 20AUG2020 FOR IMPORTANT WEAKNESS WITH BACK PAIN (BOTH CERVICAL AND LOW BACK PAIN) WITH ASSOCIATED MYALGIA (PARASPINAL, BILATERAL DELTOID). WORKING IS ONGOING. INCLUDES A NEGATIVE COVID SWAB. 21AUG2020- WAS DISCHARGED TODAY WITH LOW DOSE PREDNISONE. FEELS WAY BETTER.' reason for change: New Information	Monica Feeley (b) (4)	25 Aug 2020 21:29:16
Query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' answered with 'This met SAE reporting criteria as participant was hospitalized, thus we submitted this SAE form' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:24:07
User opened query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:23:15
Query 'PV Query: Please assess if back and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:22:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:22:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:19:58
User opened query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:19:32
User opened query 'PV Query: Please assess if back and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:07
User opened query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:46:25
User opened query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:45:17
User entered 'ADMITEED TO FAULKNER HOSPITAL TODAY FOR IMPORTANT WEAKNESS WITH BACK PAIN (BOTH CERVICAL AND LOW BACK PAIN) WITH ASSOCIATED MYALGIA (PARASPINAL, BILATERAL DELTOID). WORKING IS ONGOING. INCLUDES A NEGATIVE COVID SWAB. 21AUG2020- was discharged today with low dose prednisone. feels way better.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:24:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Aug 2020 23:39:54
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 23:39:54

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Admitted to Faulkner Hospital today for important weakness with back pain (both cervical and low back pain) with associated myalgia (paraspinal, bilateral deltoid). Working is ongoing. Includes a negative COVID swab.' reason for change: Per Query Resolution	Monica Feeley (b) (4)	20 Aug 2020 23:39:54
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Aug 2020 21:40:52
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:33:51
User entered 'USA-US078-2021-mRNA-1273-P301000011'	System	01 Feb 2021 21:30:25
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:30:25
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 21:30:25
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:11:49
User entered 'USA-US078-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	01 Feb 2021 15:11:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 13:37:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Interstitial lung disease, LLT: Interstitial pneumonitis - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 10:52:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 10:52:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'this is not a worsening of an ongoing MH condition. the term of this AE has been updated.' (Site from DM).	Monica Feeley (b) (4)	01 Apr 2021 14:30:17
Data point term sent to Coder	System	01 Apr 2021 14:29:48
Coding entries removed.	Monica Feeley (b) (4)	01 Apr 2021 14:29:46
User entered 'Idiopathic Interstitial Pneumonitis' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 14:29:46
Data point term sent to Coder	System	01 Apr 2021 13:12:41
User closed query 'For coding purposes, please split ANEMIA AND SHORTNESS OF BREATH into separate entries' (Site from System).	System	01 Apr 2021 13:11:41
Query 'For coding purposes, please split ANEMIA AND SHORTNESS OF BREATH into separate entries' answered with 'we will not split. this was one event, one hospitalization. confirmed.' (Site from System).	Monica Feeley (b) (4)	01 Apr 2021 13:11:41
User opened query 'For coding purposes, please split ANEMIA AND SHORTNESS OF BREATH into separate entries' (Site from System).	Coder Import (b) (4)	30 Mar 2021 16:14:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Requery: For coding purposes, please split or provide ONE unifying dx' canceled (Site from Coder).	(b) (4), (b) (6)	30 Mar 2021 14:25:41
User opened query 'Requery: For coding purposes, please split or provide ONE unifying dx' (Site from Coder).	(b) (4), (b) (6)	12 Mar 2021 22:04:51
User closed query 'For coding purposes, please split ANEMIA AND SHORTNESS OF BREATH into separate entries' (Site from Coder).	(b) (4), (b) (6)	12 Mar 2021 22:04:51
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 16:11:54
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:17:51
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'according to medical records, etiology is unclear' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 20:36:58
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:17:09
Query 'For coding purposes, please split □ANEMIA AND SHORTNESS OF BREATH into separate entries' answered with 'this is one event' (Site from Coder).	Monica Feeley (b) (4) (b) (4)	04 Feb 2021 18:22:56
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Jan 2021 13:16:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Jan 2021 13:16:39
User opened query 'For coding purposes, please split ANEMIA AND SHORTNESS OF BREATH into separate entries' (Site from Coder).	(b) (4), (b) (6)	31 Jan 2021 13:15:57
Data point term sent to Coder	System	29 Jan 2021 21:56:46
User entered 'Anemia and Shortness of Breath'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '28 Jan 2021'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:16:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:56:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 21:56:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:56:37
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '0'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '0'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 13:34:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'no info yet' (Site from System).	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:57:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 21:56:37
User entered 'I'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '29 Jan 2021'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:00:08
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'hospital discharge date provided' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 13:12:44
User entered '16 Feb 2021' reason for change: New Information	Monica Feeley (b) (4)	01 Apr 2021 13:12:25
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:15:57
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:15:43
User entered empty.	Monica Feeley (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '0'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '0'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '0'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered 'None (NONE)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:37:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'this has been updated to include medication and procedures' (Site from DM).	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 14:31:15
User entered '0' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 13:20:53
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:01:25
User entered '1'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 13:20:53
User entered '0'	(b) (4) Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 13:20:53
User entered '0'	(b) (4) Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:17:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41
User entered empty.	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 18:31:19
User closed query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 18:29:49
Query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' answered with 'no. these all fall under this condition. the items you listed are separate symptoms and SAEs are to be reported as a condition. confirmed. ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Apr 2021 14:44:33
Query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' answered with 'no. these all fall under this condition. the items you listed are separate symptoms and SAEs are to be reported as a condition. confirmed. ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Apr 2021 14:44:30
User opened query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:04:31
User opened query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:03:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:03:28
User closed query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:00:25
User closed query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:00:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:00:18
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)	05 Apr 2021 14:00:14
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:19:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. 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 'we have included relevant labs and diagnostic test results' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 16:26:25
User entered 'PRESENTED TO ED WITH 2 WEEKS OF WORSENING FATIGUE, GENERALIZED WEAKNESS, DYSPNEA ON EXERTION, LIGHTHEADEDNESS, DECREASED APPETITE, AND 3-4 FALLS OVER THE PAST 3 WEEKS. 2-3 DAYS AGO HAD DARK TARRY STOOL. ADMITTED TO HOSPITAL 29JAN2021.	Monica Feeley (b) (4)	01 Apr 2021 16:25:56
COVID-19 TESTS: 29JAN2021, 01FEB2021, AND 03FEB2021, ALL NEGATIVE		
Relevant lab/diagnostic tests- 07FEB21- chest CT indicates possible pneumonitis. 29JAN21- low Hgb at admission (6.9 g/dL)' reason for change: New Information		
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'all medications have been added to con medications' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 16:06:58
Query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' answered with 'please see updated AE term' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 14:31:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' answered with 'These are not separate AEs. Per participant's clinicians, these are all under this diagnosis at the moment' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 14:30:52
User opened query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:36:37
User opened query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:36:09
User closed query 'Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:18:16
Query 'Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 tests: 29JAN2021, 01FEB2021, and 03FEB2021, all negative, all NP swabs' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 21:32:02
User entered 'PRESENTED TO ED WITH 2 WEEKS OF WORSENING FATIGUE, GENERALIZED WEAKNESS, DYSPNEA ON EXERTION, LIGHTHEADEDNESS, DECREASED APPETITE, AND 3-4 FALLS OVER THE PAST 3 WEEKS. 2-3 DAYS AGO HAD DARK TARRY STOOL. ADMITTED TO HOSPITAL 29JAN2021.	Monica Feeley (b) (4)	10 Feb 2021 21:31:39
COVID-19 tests: 29JAN2021, 01FEB2021, and 03FEB2021, all negative' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:17:36
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)	05 Feb 2021 18:17:18
User opened query 'Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:15:34
User entered 'Presented to ED with 2 weeks of worsening fatigue, generalized weakness, dyspnea on exertion, lightheadedness, decreased appetite, and 3-4 falls over the past 3 weeks. 2-3 days ago had dark tarry stool. Admitted to hospital 29JAN2021.'	Monica Feeley (b) (4) (b) (4)	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 21:56:56

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 21:56:37

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:04
User entered 'USA-US078-2021-mRNA-1273-P301000020'	System	06 Apr 2021 18:32:59
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 18:32:59

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual disorders NEC, PT: Diplopia, LLT: Diplopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:50:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:50:25
Data point term sent to Coder	System	05 Apr 2021 16:49:02
User entered 'Diplopia'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '31 Mar 2021'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:28:03
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Apr 2021 13:37:29
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not known yet' (Site from System).	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:49:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Apr 2021 16:48:14
User entered 'I'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '04 Apr 2021'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '07 Apr 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	08 Apr 2021 13:40:12
User entered empty.	(b) (4)	
	Monica Feeley (b) (4)	05 Apr 2021 16:48:14
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'None (NONE)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:28:45
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:28:54
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:28:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered 'l'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:28:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: The source documents note that the patient received treatment for idiopathic interstitial pneumonitis and polymyalgia rheumatica. However, neither of these conditions is reported as medical history. Please consider whether the medical history should be updated to include these conditions and update the report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 18:43:25
Query 'PV query: The source documents note that the patient received treatment for idiopathic interstitial pneumonitis and polymyalgia rheumatica. However, neither of these conditions is reported as medical history. Please consider whether the medical history should be updated to include these conditions and update the report if appropriate.' answered with '?? how is this medical history, there are clearly SAEs for these two conditions recorded in the database?' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	19 Apr 2021 14:43:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:27:15
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:31:40
User opened query 'PV query: The source documents note that the patient received treatment for idiopathic interstitial pneumonitis and polymyalgia rheumatica. However, neither of these conditions is reported as medical history. Please consider whether the medical history should be updated to include these conditions and update the report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:29:54
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:27:26
User entered 'participant presented to hospital 04APR2021 with 5 days of diplopia'	Monica Feeley (b) (4) (b) (4)	05 Apr 2021 16:48:14
PRODUCTION RELEASE (v12.003 EAB) (1725)		2233 of 3118

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 16:48:14

US3432023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:36:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 16:48:14

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:51
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:29:41
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:03:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 12:20:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 12:20:11
Data point term sent to Coder	System	05 Aug 2020 23:05:28
User entered 'Aspirin'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Stroke'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '325'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:10:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:12:07
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:04:47
User entered 'UN UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:04:47
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:44
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:25 26 Oct 2020 17:21:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:05
Data point term sent to Coder User entered 'Plavix'	System Monica Feeley (b) (4)	05 Aug 2020 23:06:29 05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Stroke'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '75'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:10:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:29
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:06:04
User entered 'UN UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:35
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:29 26 Oct 2020 17:21:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:06
Data point term sent to Coder User entered 'Bupropion'	System Monica Feeley (b) (4)	05 Aug 2020 23:07:30 05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Depression'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '150'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:35
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:06:44
User entered 'un UNK 1980'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:45
Data point term sent to Coder	System	26 Oct 2020 17:21:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 15:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 15:58:11
Data point term sent to Coder	System	05 Aug 2020 23:07:30
User entered 'Multivitamin'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'l'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'tablet (TABLET)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:39
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:07:12
User entered 'Un UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:42
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:25 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
Data point term sent to Coder User entered 'Vitamin D'	System Monica Feeley (b) (4)	05 Aug 2020 23:08:30 05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2000'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'IU (IU)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:44
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:07:45
User entered 'UN UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:07:45
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:34
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:23 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
Data point term sent to Coder User entered 'Calcium'	System Monica Feeley (b) (4)	05 Aug 2020 23:08:31 05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '1000'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:49
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:08:12
User entered 'Un UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:08:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:15:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:15:46
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:28:52 10 Nov 2020 21:28:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:25
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:31 26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:37:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:37:02
Data point term sent to Coder User entered 'bisoprolol'	System Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:31 05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:30:40
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Nov 2020 21:28:33
User entered 'HEART FAILURE/HTN' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Monica Feeley (b) (4)	10 Nov 2020 21:28:33
	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Heart failure'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2.5'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:25:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'date correct . This is also taken for hypertension which started in 2010' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:28:20
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:59:04
User closed query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:51:13
Query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' answered with 'per protocol required' (Site from DM).	Xhoi Mitre (b) (4)	11 Aug 2020 17:30:18

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 10:46:51
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:45:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:11:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:09:13
User entered 'UN UNK 2016'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN Jul 2020'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User entered 'l'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User entered 'l'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:07
User entered '804 (804)'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
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.	Coder Import (b) (4)	26 Oct 2020 18:05:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:39
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:30 26 Oct 2020 17:21:22
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.	Coder Import (b) (4)	06 Aug 2020 00:56:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:56:02
Data point term sent to Coder User entered 'Levothyronine'	System Monica Feeley (b) (4)	05 Aug 2020 23:10:32 05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'hypothyroidism'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:43
Query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'this is what the participant reported' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:22:50
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.'	(b) (4), (b) (6)	04 Nov 2020 11:59:12
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:01:02
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.'	Megan Powell (b) (4)	21 Oct 2020 22:46:52
' answered with 'Dose provided by participant' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.'	(b) (4), (b) (6)	01 Oct 2020 03:47:39
(Site from DM).		
User entered '1.2'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'ug (ug)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:13
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:10:28
User entered 'Un UNK 2005'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	05 Aug 2020 23:10:28
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 01:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 01:49:15
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Nov 2020 15:26:14 23 Nov 2020 15:25:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:23
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:30 26 Oct 2020 17:21:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 17:31:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 17:31:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 17:30:17
User entered 'Aspirin'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:29:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 17:29:42
User entered 'No (N)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:42
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:29:25
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:32:00
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per CDM re-query: Thank you for the confirmation. Please update the indication so that there will be an exact match in CM and MH form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:44:37
Query 'Per CDM re-query: Thank you for the confirmation. Please update the indication so that there will be an exact match in CM and MH form. Thank you. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:25:39
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:25:29
User entered 'CHRONIC LOW BACK PAIN WITH INTERMITTENT FLARE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:25:29
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:04
User opened query 'Per CDM re-query: Thank you for the confirmation. Please update the indication so that there will be an exact match in CM and MH form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:02
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'please read "chronic low back pain"' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:22:06
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:58:20

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User entered 'Back pain'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '325'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol required' (Site from System).	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:29:25
User entered 'UN UNK 2000'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
	(b) (4), (b) (6)	
User entered '0'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:05:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:47
Data point term sent to Coder	System	26 Oct 2020 17:21:30
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'per clinician, participant met eligibility criteria. Medication and diagnosis began after visit 1 ' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 22:52:19
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:52:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 08:29:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 08:29:44
Data point term sent to Coder	System	31 Aug 2020 20:48:44
User entered 'prednisone'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'possible polymyalgia rheumatica'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '21 Aug 2020'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)' reason for change: New Information	Phoebe Cunningham (b) (4)	12 Sep 2020 12:50:49
User entered 'Yes (Y)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Sep 2020 15:27:02
User entered '04 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	12 Sep 2020 15:27:02
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Sep 2020 12:50:49
User entered 'un UNK 2020' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	12 Sep 2020 12:50:49
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User entered 'I'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User entered 'l'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:20
User entered '804 (804)'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:48
Data point term sent to Coder	System	26 Oct 2020 17:21:31
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 08:29:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 08:29:46
Data point term sent to Coder	System	31 Aug 2020 20:49:45
User entered 'prednisone'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'possible polymyalgia rheumatica'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '15'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once (ONCE)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20 Aug 2020'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20 Aug 2020'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:22:24
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'does not' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:12:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Monica Feeley (b) (4)	10 Nov 2020 21:29:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:29
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:32
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:52:38

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 12:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 12:53:46
Data point term sent to Coder	System	12 Sep 2020 12:53:06
User entered 'Prednisone'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'POLYMYALGIA RHEUMATICA'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '11 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:31
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:32 26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 19:28:41
Data point term sent to Coder User entered 'Rosuvastatin'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:51 12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Hyperlipidemia'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '40'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:27:43
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:27:43
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:27:43
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2018'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:27:43
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:33 26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 00:44:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 00:44:36
Data point term sent to Coder User entered 'Atenolol'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:57 12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Premature ventricular complex'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2010'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:36:12
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:31 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 20:41:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 20:41:40
Data point term sent to Coder User entered 'Colase'	System Monica Feeley (b) (4)	12 Sep 2020 19:37:58 12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Constipation'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UNK'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:02
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN Jan 2020'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:02
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:41
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:34 26 Oct 2020 17:21:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 19:38:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 19:38:35
Data point term sent to Coder User entered 'Flonase'	System Monica Feeley (b) (4)	12 Sep 2020 19:37:58 12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:22:18
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'added' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:27:01
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:32:11
User entered 'seasonal allergies'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'puff (PUFF)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Nasal (NASAL)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2010'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered '0'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
DataPoint Verified.		
User entered empty.	Monica Feeley (b) (4)	12 Sep 2020 19:37:40
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:28
Data point term sent to Coder	System	26 Oct 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:30:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:30:52
Data point term sent to Coder	System	01 Oct 2020 20:30:21
User entered 'Flu vaccine'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'prophylaxis for influenza'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'l'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'injection'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once (ONCE)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Intramuscular (INTRAMUSCULAR)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25 Sep 2020'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25 Sep 2020'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Julia Klopfer (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:47
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:11:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:52:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:52:41
Data point term sent to Coder	System	01 Apr 2021 14:52:12
User entered 'Zofran'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Nausea'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '4'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'every 6 hours PRN'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
User entered empty.	System	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
User entered empty.	System	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:27
User entered empty.	System	01 Apr 2021 14:52:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:12:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:54:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:54:34
Data point term sent to Coder	System	01 Apr 2021 14:53:14
User entered 'zofran'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'nausea'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '2'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'every 4 hours PRN'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
User entered empty.	System	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
User entered empty.	System	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:31
User entered empty.	System	01 Apr 2021 14:52:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 12:53:32
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 Apr 2021 12:53:32
Data point term sent to Coder Coding entries removed.	System Jessica Cauley (b) (4) (b) (4)	19 Apr 2021 12:52:00 19 Apr 2021 12:51:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:01
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 12:46:01
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:12:30
Data point term sent to Coder User entered 'Methylprednisolone'	System Monica Feeley (b) (4) (b) (4)	01 Apr 2021 14:54:14 01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:52:03
User closed query 'Should be PMR. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:52:00
Query 'Should be PMR. ' answered with 'updated' (Site from CRA).	Jessica Cauley (b) (4)	19 Apr 2021 12:52:01
Signature has been broken.	Jessica Cauley (b) (4)	19 Apr 2021 12:51:46
User entered 'PMR' reason for change: Data Entry Error	Jessica Cauley (b) (4)	19 Apr 2021 12:51:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User opened query 'Should be PMR. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:47:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PRM'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '4'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '08 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:56:56
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
User entered 'l'	System	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
User entered 'I'	System	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:38
User entered '804 (804)'	System	01 Apr 2021 14:53:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:13:53
Data point term sent to Coder	System	01 Apr 2021 14:54:15
User entered 'methylprednisolone'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PMR'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '12'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '30 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '08 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
User entered 'I'	System	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
User entered 'I'	System	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:51
User entered '804 (804)'	System	01 Apr 2021 14:54:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:14:13
Data point term sent to Coder	System	01 Apr 2021 14:55:16
User entered 'methylprednisolone'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PMR'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '2'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '06 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
User entered 'l'	System	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
User entered 'I'	System	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:34
User entered '804 (804)'	System	01 Apr 2021 14:54:33

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:15:39
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:56:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:56:36
Data point term sent to Coder	System	01 Apr 2021 14:55:16
User entered 'metamucil'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'constipation'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'l'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'packet'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '31 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
User entered 'l'	System	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
User entered 'I'	System	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:40
User entered '804 (804)'	System	01 Apr 2021 14:55:06

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
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)	05 Apr 2021 11:04:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:04:21
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 14:56:17
User entered 'heparin'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'coagulant prophylaxis'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '5000'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Units'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'three times daily (TID)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
User entered '3'	System	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
User entered 'l'	System	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:46
User entered '804 (804)'	System	01 Apr 2021 14:55:48

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:58:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:58:32
Data point term sent to Coder	System	01 Apr 2021 14:57:18
User entered 'mucinex'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'cough'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '600'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:52:24
User closed query 'Twice daily PRN.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:52:22
Query 'Twice daily PRN.' answered with 'updated' (Site from CRA).	Julia Klopfer (b) (4)	19 Apr 2021 14:35:10
Signature has been broken.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:04
User entered 'other (OTHER)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Apr 2021 14:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User opened query 'Twice daily PRN.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:54:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:52:26
DataPoint Un-verified.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:04
Signature has been broken.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:04
User entered 'twice daily as needed' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Apr 2021 14:35:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:57:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
User entered empty.	System	19 Apr 2021 14:35:04
User entered '2'	System	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
User entered empty.	System	19 Apr 2021 14:35:04
User entered '1'	System	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:52
User entered empty.	System	19 Apr 2021 14:35:04
User entered '804 (804)'	System	01 Apr 2021 14:56:22

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:58:33
Data point term sent to Coder	System	01 Apr 2021 14:57:18
User entered 'acetaminophen'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'pain and fever'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '650'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'every 6 hours PRN'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '04 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
User entered empty.	System	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
User entered empty.	System	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:59
User entered empty.	System	01 Apr 2021 14:57:07

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: XANTHINES, PRODUCT: AMINOPHYLLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:13:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:13:56
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 15:36:06
User entered 'aminophylline'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'idiopathic interstitial pneumonitis'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '50'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once (ONCE)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '31 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '31 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
User entered empty.	System	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
User entered empty.	System	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:21:04
User entered empty.	System	01 Apr 2021 15:35:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE, PRODUCTSYNONYM: AFRIN [OXYMETAZOLINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:06:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:06:54
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 15:37:07
User entered 'Afrin'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'idiopathic interstitial pneumonitis'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0.05'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Percent'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:52:55
User closed query 'Twice daily PRN. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:52:52
Query 'Twice daily PRN. ' answered with 'updated' (Site from CRA).	Julia Klopfer (b) (4)	19 Apr 2021 14:35:54
Signature has been broken.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:49
User entered 'other (OTHER)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Apr 2021 14:35:49
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User opened query 'Twice daily PRN. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:00:11
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:52:57
DataPoint Un-verified.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:49
Signature has been broken.	Julia Klopfer (b) (4)	19 Apr 2021 14:35:49
User entered 'twice daily as needed' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Apr 2021 14:35:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Nasal (NASAL)'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '02 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 15:37:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 15:37:57
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 15:37:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 15:36:13
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '05 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:05:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
User entered empty.	System	19 Apr 2021 14:35:49
User entered '2'	System	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
User entered empty.	System	19 Apr 2021 14:35:49
User entered '1'	System	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:32
User entered empty.	System	19 Apr 2021 14:35:49
User entered '804 (804)'	System	01 Apr 2021 15:36:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:04:59
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 15:38:08
User entered 'Albuterol'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Wheezing associated with idiopathic interstitial pneumonitis'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '2'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'puff (PUFF)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'every 4 hours PRN'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
User entered empty.	System	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
User entered empty.	System	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:55
User entered empty.	System	01 Apr 2021 15:37:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, ATC: OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, PRODUCT: ATOVAQUONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 01:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 01:49:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
Data point term sent to Coder	System	22 Apr 2021 20:28:27
Coding entries removed.	Monica Feeley (b) (4)	22 Apr 2021 20:27:36
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, ATC: OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, PRODUCT: ATOVAQUONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:23:50
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 15:38:08
User entered 'Atovaquone'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PJP prophylaxis'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '750/5'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg/mL'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User closed query 'Should be IV per medical records. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:08:47
Query 'Should be IV per medical records. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	22 Apr 2021 20:27:41
Signature has been broken.	(b) (4)	
	Monica Feeley (b) (4)	22 Apr 2021 20:27:36
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Monica Feeley (b) (4)	22 Apr 2021 20:27:36
User opened query 'Should be IV per medical records. ' (Site from CRA).	(b) (4)	
Query 'IV per medical records. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:11:04
User opened query 'IV per medical records. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:09:17
User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 15:07:07
	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
	(b) (4)	
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User closed query '8-Feb-21 per medical records. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:08:49
Query '8-Feb-21 per medical records. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	22 Apr 2021 20:27:57
Signature has been broken.	(b) (4)	
	Monica Feeley (b) (4)	22 Apr 2021 20:27:52
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User opened query '8-Feb-21 per medical records. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:11:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '06 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User closed query 'No per medical records. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:08:51
Query 'No per medical records. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	22 Apr 2021 20:28:00
Signature has been broken.	Monica Feeley (b) (4)	22 Apr 2021 20:27:52
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	22 Apr 2021 20:27:52
User opened query 'No per medical records. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:11:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User closed query '11-Feb-21 per medical records.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:08:56
Query '11-Feb-21 per medical records.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	22 Apr 2021 20:28:01
Signature has been broken.	(b) (4)	
	Monica Feeley (b) (4)	22 Apr 2021 20:27:52
	(b) (4)	
User entered '11 Feb 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	22 Apr 2021 20:27:52
User opened query '11-Feb-21 per medical records.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:11:46
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 15:37:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:09:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User entered '2'	System	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User entered 'l'	System	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:19:11
User entered '804 (804)'	System	01 Apr 2021 15:37:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:37:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:37:15
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:28:37
Data point term sent to Coder	System	01 Apr 2021 16:45:05
User entered 'SOLU-Medrol'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PMR'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '24'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '08 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '11 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
User entered '2'	System	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
User entered 'l'	System	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:17:39
User entered '804 (804)'	System	01 Apr 2021 16:44:17

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Apr 2021 16:45:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Apr 2021 16:45:38
Data point term sent to Coder	System	01 Apr 2021 16:45:05
User entered 'Prednisone'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PMR'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '40'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '11 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:08:28
User closed query 'End date per medical records is 15-Feb-21. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:08:26
Query 'End date per medical records is 15-Feb-21. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	22 Apr 2021 20:28:57
Signature has been broken.	(b) (4)	
	Monica Feeley (b) (4)	22 Apr 2021 20:28:54
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	22 Apr 2021 20:28:54
	(b) (4), (b) (6)	14 Apr 2021 15:14:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User opened query 'End date per medical records is 15-Feb-21. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:13:21
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
User entered 'l'	System	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
User entered 'I'	System	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:18:32
User entered '804 (804)'	System	01 Apr 2021 16:44:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids \geq 20 mg/day of prednisone equivalent). ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:29:10
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids \geq 20 mg/day of prednisone equivalent). ' answered with 'This medication does not meet exclusion criteria because exclusion criteria specifies that systemic immunosuppressants or immune-modifying drugs were within 6 months PRIOR to screening. This medication was taken after screening. ' (Site from DM).	Austin Kim (b) (4) (b) (4)	26 Apr 2021 14:40:11
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids \geq 20 mg/day of prednisone equivalent). ' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 18:56:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 16:46:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Apr 2021 16:46:28
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	01 Apr 2021 16:46:07
User entered 'Prednisone'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'PMR'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '40'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:33:04
User closed query 'start date per medical records is 15Feb-21. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:33:02
Query 'start date per medical records is 15Feb-21. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	14 Apr 2021 20:37:06
Signature has been broken.	(b) (4)	
	Monica Feeley (b) (4)	14 Apr 2021 20:36:52
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User opened query 'start date per medical records is 15Feb-21. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:13:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '03 Mar 2021'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
User entered '1'	System	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
User entered '1'	System	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:36:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:20:21
User entered '804 (804)'	System	01 Apr 2021 16:45:19

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:36:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 13:34:02
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 18:11:51

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:35:26

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'CARDIAC ULTRASOUND' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 16:06:02
User entered 'cardia ultrasound'	Monica Feeley (b) (4)	01 Apr 2021 13:35:26
	(b) (4)	

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:35:26

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:50

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
	(b) (4), (b) (6)	01 Apr 2021 19:15:52
DataPoint Verified.	Monica Feeley (b) (4)	01 Apr 2021 13:35:26
User entered empty.	(b) (4)	

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:35:39

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'chest XR'	Monica Feeley (b) (4)	01 Apr 2021 13:35:39

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:35:39

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:35:39

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '29 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:36:02

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'CT head'	Monica Feeley (b) (4)	01 Apr 2021 13:36:02

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:36:02

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:36:02

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '31 Jan 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:36:52

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Myocardial perfusion SPECT study'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 13:36:52

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:36:52

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:36:52

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '02 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:37:24

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Lung ventilation and Perfusion scan'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 13:37:24

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:37:24

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:37:24

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:37:40

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'CT Chest'	Monica Feeley (b) (4)	01 Apr 2021 13:37:40

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:37:40

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:37:40

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:36:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered '16 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 13:37:58

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:36:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Abdomen Ultrasound'	Monica Feeley (b) (4)	01 Apr 2021 13:37:58

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:36:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 13:37:58

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:36:50

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:50:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:15:52
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 13:37:58

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:43:15
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '26 Aug 2020'	Monica Feeley (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:43:15
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'SAE (specify) (SAE)'	Monica Feeley (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:43:15
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:12:38
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	24 Nov 2020 14:36:48
User entered 'SAE #1' reason for change: Per Query Resolution	Alexander Mills (b) (4)	24 Nov 2020 14:36:42
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:08:04
User entered 'Possible Polymyalgia Rheumatica'	Monica Feeley (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden(b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden(b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:02
User entered '21/Aug/2020 09:37'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:05
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'l'	(b) (4), (b) (6)	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:17
User entered '24/Aug/2020 11:19'	System	24 Aug 2020 15:19:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:24
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'l'	(b) (4), (b) (6)	24 Aug 2020 15:19:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:29
User entered '26/Aug/2020 10:11'	System	26 Aug 2020 14:11:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 13:42:55
User entered 'l'	(b) (4), (b) (6)	26 Aug 2020 14:11:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:36
User entered '27/Aug/2020 09:43'	System	27 Aug 2020 13:43:11

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:38
User entered 'l'	(b) (4), (b) (6)	27 Aug 2020 13:43:11

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '17/Sep/2020 08:34'	System	17 Sep 2020 12:34:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:42:52
User entered 'I'	(b) (4), (b) (6)	17 Sep 2020 12:34:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '15/Oct/2020 09:43'	System	15 Oct 2020 13:43:02

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:16:36
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 13:43:02

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '22/Oct/2020 20:16'	System	22 Oct 2020 20:16:53

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
	(b) (4), (b) (6)	26 Oct 2020 17:30:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:17:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:16:53
User entered 'l'		

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE-USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '8'	System	01 Feb 2021 15:12:25
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '01/Feb/2021 15:12'	System	01 Feb 2021 15:12:25

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 15:12:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'USA-US078-2021-MRNA-1273-P301000011'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Lindsey'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Baden'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'MA'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'US'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 18:39:46
User entered '3'	System	01 Apr 2021 20:07:08
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '2'	System	11 Feb 2021 16:21:32
User entered '1'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'USA-US078-2021-MRNA-1273-P301000011'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Lindsey'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Baden'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'MA'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'US'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 18:39:46
User entered '3'	System	01 Apr 2021 20:07:08
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '2'	System	11 Feb 2021 16:21:32
User entered '1'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '01/Feb/2021 21:38'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

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)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'l'	(b) (4), (b) (6)	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'USA-US078-2021-MRNA-1273-P301000011'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Lindsey'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Baden'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'MA'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'US'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 18:39:46
User entered '3'	System	01 Apr 2021 20:07:08
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '2'	System	11 Feb 2021 16:21:32
User entered '1'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '11/Feb/2021 11:21'	System	11 Feb 2021 16:21:32

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

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)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 16:21:32

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'USA-US078-2021-MRNA-1273-P301000011'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Lindsey'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Baden'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'MA'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'US'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 18:39:46
User entered '3'	System	01 Apr 2021 20:07:08
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '2'	System	11 Feb 2021 16:21:32
User entered '1'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered '01/Apr/2021 13:07'	System	01 Apr 2021 20:07:08

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	04 Apr 2021 20:28:37
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 20:07:08

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'USA-US078-2021-MRNA-1273-P301000011'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Yes (Y)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'No (N)'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Lindsey'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'Baden'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 21:38:32
User entered 'MA'	System	01 Feb 2021 21:30:25

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:13:16
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'US'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 18:39:46
User entered '3'	System	01 Apr 2021 20:07:08
User signature succeeded.	Lindsey Baden (b) (4)	15 Feb 2021 23:34:24
User entered '2'	System	11 Feb 2021 16:21:32
User entered '1'	System	01 Feb 2021 21:38:39

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
User entered '20/Apr/2021 11:39'	System	20 Apr 2021 18:39:46

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 18:39:46

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:47
User entered 'USA-US078-2021-MRNA-1273-P301000020'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Lindsey'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Baden'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'MA'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:56:59
User entered 'US'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 18:57:24
User entered '1'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:47
User entered 'USA-US078-2021-MRNA-1273-P301000020'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Lindsey'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Baden'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'MA'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:56:59
User entered 'US'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 18:57:24
User entered '1'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
User entered '06/Apr/2021 14:40'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:56:59
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:57:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:47
User entered 'USA-US078-2021-MRNA-1273-P301000020'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Yes (Y)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'No (N)'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Lindsey'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'Baden'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:40:50
User entered 'MA'	System	06 Apr 2021 18:32:59

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:56:59
User entered 'US'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 18:57:24
User entered '1'	System	06 Apr 2021 18:40:58

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
User entered '08/Apr/2021 14:57'	System	08 Apr 2021 18:57:24

US3432023

Folder: SAE USA-US078-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:50

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.	Lindsey Baden (b) (4)	25 Apr 2021 10:56:39
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 18:57:24