

US3432202 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:02

All time stamps listed in this document are displayed in GMT

US3432202

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 01:58:59

Generated On: 09 Jun 2021 17:34:02

Participant ID

US3432202

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

US3432202

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	19 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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US3432202

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3432202

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3432202

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	DIABETES MELLITUS
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)	_____

US3432202

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	ANXIETY
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)	

US3432202

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	HIGH CHOLESTEROL (HLD)
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)	

US3432202

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	CHRONIC FATIGUE (BEING FOLLOWED BY PHYSICIAN)
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 (7)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	NECK PAIN { BEING FOLLOWED BY MD }
Start date (dd MMM yyyy)	UN MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	GAIT INSTABILITY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3432202

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	CHOREA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3432202

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	HYPERTENSION
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)	

US3432202

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	L VERTEBRAL ARTERY DISSECTION
Start date (dd MMM yyyy)	UN UNK 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 UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	ACUTE KIDNEY INJURY
Start date (dd MMM yyyy)	28 JAN 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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432202

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Condition	EYELID RETRACTION L EYE
Start date (dd MMM yyyy)	03 OCT 2016
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)	03 OCT 2016
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	OCT 2016
Stop Year (derived)	2016

US3432202

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:43 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:43
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	81.7 kg
BMI (<i>xxx.x</i>)	26.98507 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432202

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

US3432202

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3432202

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	19 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	VISIT1
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US3432202

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187067

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Height	ND - Not Done
Weight	ND - Not Done

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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)	19 AUG 2020
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:43
Temperature (xxx.x)	37.2 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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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)	19 AUG 2020
Time of assessment (00:00-23:59)	16:09 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:09
Temperature (xxx.x)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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.

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 15:39

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) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:55

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:02	19 AUG 2020 15:02
Nasopharyngeal Swab 2	No		

US3432202

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

99.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 19 AUG 2020 16:10

PC Open Date & Time 19 AUG 2020 15:59

PC Close Date & Time 19 AUG 2020 18:29

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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 98.7 °F

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

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

PC Time Stamp	19 AUG 2020 20:06
PC Open Date & Time	19 AUG 2020 19:24
PC Close Date & Time	20 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 22:02

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

99.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 21:08

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 20:08

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

23 AUG 2020 19:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

25 AUG 2020 00:03

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

25 AUG 2020 22:28

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

19 AUG 2020 16:13

PC Open Date & Time

19 AUG 2020 15:59

PC Close Date & Time

19 AUG 2020 18:29

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

19 AUG 2020 20:07

PC Open Date & Time

19 AUG 2020 19:24

PC Close Date & Time

20 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

20 AUG 2020 22:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

21 AUG 2020 21:09

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

22 AUG 2020 20:08

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

23 AUG 2020 19:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

25 AUG 2020 00:04

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

25 AUG 2020 22:28

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:14
PC Open Date & Time	19 AUG 2020 15:59
PC Close Date & Time	19 AUG 2020 18:29

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 20:09
PC Open Date & Time	19 AUG 2020 19:24
PC Close Date & Time	20 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

		Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 22:05	
PC Open Date & Time	20 AUG 2020 12:00	
PC Close Date & Time	21 AUG 2020 11:59	

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

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EAB) (1725)

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

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)

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 00:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

67 of 2725

EAB) (1725)

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 22:29
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 26 AUG 2020 22:14

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 26 AUG 2020 22:14

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 27 AUG 2020 12:01

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:12

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 AUG 2020 19:53

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 15:40

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:26

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 AUG 2020 22:14
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 21:12
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 12:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 19:53
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 15:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 12:26
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3432202

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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 SEP 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 13:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	061 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 16:00
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	IR
Pulse (xxx)	096 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)	067 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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) 16 SEP 2020

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

Treatment Date and Time (derived) 16 SEP 2020 15:24

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

What was the frequency of the study treatment dosing? ONCE

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

US3432202

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	14:20 (24 HR)
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Collection date and time (derived)	16 SEP 2020 14:20
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US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:22	16 SEP 2020 14:22
Nasopharyngeal Swab 2	No		

US3432202

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 16 SEP 2020 16:09

PC Open Date & Time 16 SEP 2020 15:44

PC Close Date & Time 16 SEP 2020 18:14

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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 99.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 16 SEP 2020 21:48

PC Open Date & Time 16 SEP 2020 19:09

PC Close Date & Time 17 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

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):

PC Time Stamp

17 SEP 2020 12:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

96.6 °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

19 SEP 2020 00:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 22:39

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

20 SEP 2020 22:11

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 16:20

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 16:10

PC Open Date & Time

16 SEP 2020 15:44

PC Close Date & Time

16 SEP 2020 18:14

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

16 SEP 2020 21:48

PC Open Date & Time

16 SEP 2020 19:09

PC Close Date & Time

17 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

17 SEP 2020 12:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 00:09

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

19 SEP 2020 22:40

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

20 SEP 2020 22:12

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

22 SEP 2020 19:55

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 16:11
PC Open Date & Time	16 SEP 2020 15:44
PC Close Date & Time	16 SEP 2020 18:14

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:49
PC Open Date & Time	16 SEP 2020 19:09
PC Close Date & Time	17 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

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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US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

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)

120 of 2725

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 00:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

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 ☒

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 22:41
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

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 ☒

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:13
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

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 ☒

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:56
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432202

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 SEP 2020

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

Comments CALLED PT. 9/25/2020 AT
6:30PM, 9/26/2020 AT 11:59AM
AND 2:51PM. ALSO EMAILED
PARTICIPANT ON 9/26/2020.

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments PT. CALLED ON 29SEP2020 AT
10:22AM, 30SEP2020 AT 6:34PM,
AND 01OCT2020 AT 10:55AM
AND 4:35PM. PT ALSO EMAILED
ON 01OCT2020 AND NO
CONTACT WAS MADE.

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments PARTICIPANT CALLED 9:06
AND 13:48 ON 06OCT2020, 10:30
If Contact Not Made, please provide Comments AND 17:39 ON 07OCT2020, AND
9:44 08OCT2020

US3432202

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 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

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 13:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	097 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)	068 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432202

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

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.

US3432202

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	2 NOV 2020
-------------------------------	------------

Collection time (00:00-23:59)	13:50 (24 HR)
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Collection date and time (derived)	2 NOV 2020 13:50
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US3432202

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:01

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 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	21 OCT 2020 09:11:34
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:16:59

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 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	04 NOV 2020 11:56:04
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	16 NOV 2020 15:17:29
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 12:24:55
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 00:20:51

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 21:53:09

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 13:32:23

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 23:04:41

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

26 DEC 2020 18:27:17

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 20:59:30

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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 JAN 2021 22:38:44
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

17 JAN 2021 17:44:35

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 20:54:45

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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	30 JAN 2021 00:19:58
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

05 FEB 2021 00:01:36

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 19:53:09
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 11:23:06
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 00:27:22

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 00:01:28

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 00:07:56

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 22:32:06

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

06 APR 2021 11:59:57

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 12:04:29

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 12:41:57

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 00:47:44

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 20:15:11

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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 <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"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	25 OCT 2022 23:59
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US3432202

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:02

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		02 MAR 2021 11:23:25

US3432202

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	15 MAR 2021
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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	VISIT4
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US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:36
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432202

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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.

US3432202

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 15 MAR 2021

Collection time (00:00-23:59) 14:15 (24 HR)

Collection date and time (derived) 15 MAR 2021 14:15

US3432202

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432202

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:34:02

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432202

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	25 JAN 2021
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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	UNBLND_DECIDE
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US3432202

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3432202

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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

US3432202

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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)	25 JAN 2021
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 14:09
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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)	25 JAN 2021
Time of assessment (00:00-23:59)	15:23 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 15:23
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3432202

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 14:51 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 14:51

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

US3432202

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00-23:59)	14:04 (24 HR)
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Collection date and time (derived)	25 JAN 2021 14:04
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US3432202

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 25 JAN 2021

Collection time (00:00 - 23:59) 14:07

Collection Date and Time (derived) 25 JAN 2021 14:07

US3432202

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3432202

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	01 MAR 2021
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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	OLD29
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US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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)	01 MAR 2021
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 16:24
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	094 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	01 MAR 2021
Time of assessment (00:00-23:59)	17:26 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 17:26
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

US3432202

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 MAR 2021

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

US3432202

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 16:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3432202

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432202

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432202

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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

Visit date (dd MMM yyyy)	29 MAR 2021
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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	OLD57
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US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 13:12
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432202

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

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.

US3432202

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:24

Generated On: 09 Jun 2021 17:34:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	29 MAR 2021
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Collection time (00:00-23:59)	13:23 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	29 MAR 2021 13:23
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US3432202

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 01:58:59

Generated On: 09 Jun 2021 17:34:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

AEID

Adverse event

FOREIGN BODY IN FOOT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

2 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

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 type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

AEID	USA-US078-2020-MRNA-1273-P30 1000003
Adverse event	HYPERTENSIVE URGENCY
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

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

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

PT RECEIVED SECOND
VACCINE 16SEP2020. PATIENT
WAS FOUND THIS MORNING
WALKING OUTSIDE
DISORIENTED BY A
BYSTANDER WHO CALLED
EMS. ALSO REPORTS
DIZZINESS. WAS ADMITTED
TODAY BECAUSE OF THE
CONFUSION. HAD A CEREBRAL
SCAN WITHOUT SIGNIFICANT
CHANGES FROM PREVIOUS
SCAN DONE IN 2019. HAD HTN
IN THE ED (UP TO 204
SYSTOLIC) HE IS KNOWN WITH
HTN, WHICH IS CAPTURED IN
THE MEDICAL HISTORY.
02 OCT 2020- SAE DISCHARGE
UPDATE: PT WAS
HOSPITALIZED FROM 9/25 TO
9/30 FOR CONFUSION IN THE
CONTEXT OF UNCONTROLLED
HYPERTENSION. BP WAS
CONTROLLED DURING
HOSPITALIZATION WITH
LISINOPRIL 5MG QD WHICH
MUCH IMPROVEMENT. PT WAS
BACK TO BASELINE AT
DISCHARGE.
30OCT2020 UPDATED: HEAD CT
(25SEP2020), CHEST XR
(25SEP2020), BRAIN MRI
(25SEP2020), CERVICAL SPINE
MRI (28SEP2020) - ALL IMAGING
SHOWED NO ACUTE FINDING

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

THAT CAN EXPLAIN
CONFUSION. EEG (29SEP2020) -
NO EPILEPTIFORM OR
LATERALIZING
ABNORMALITIES
LP (26SEP2020) - WBC COUNT
OF 1, HSV PCR NEGATIVE,
VIRAL CULTURE NEGATIVE,
BACTERIA CULTURE
NEGATIVE

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

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

AEID

Adverse event

CERVICAL STENOSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

AEID

Adverse event

BASAL CELL CARCINOMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

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

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 20:40:23

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication GLYBURIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (2)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (3)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (4)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication	PROZAC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (5)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (6)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication DUODENAL ULCER

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (7)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication NSAIDS

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FOREIGN BODY IN FOOT

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		1 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 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 (10)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		27 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 (11)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 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"/>

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

TWICE

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

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US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 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 (13)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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 (14)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 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 (15)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MILD PAIN IN HOSPITAL (SAE:
HYPERTENSIVE URGENCY)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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 (16)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (16)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 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 (17)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MILD GENERAL PAIN WHILE IN
HOSPITAL (SAE HYPERTENSIVE
URGENCY)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 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 (18)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication SENOKOT

Prophylaxis Yes ☐
No ☒

Indication MILD CONSTIPATION

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 (18)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PREVENTION

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 (19)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 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"/>

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DM

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 (20)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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 (21)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY AND DEPRESSION

Dose per administration 100

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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US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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"/>

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 30

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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US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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"/>

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

8X DAILY

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 04 Apr 2021 20:40:23

Generated On: 09 Jun 2021 17:34:02

	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) _____		
Start date completely unknown		True
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"/>

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Apr 2021 11:07:08

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 AUG 2020	FOREIGN BODY REMOVAL FROM FOOT	Adverse Event	
25 SEP 2020	CT HEAD AND NECK	Adverse Event	
25 SEP 2020	MRI BRAIN	Adverse Event	
28 SEP 2020	MRI NECK	Adverse Event	
25 SEP 2020	CHEST X-RAY	Adverse Event	
25 SEP 2020	ECG	Adverse Event	
29 SEP 2020	EEG	Adverse Event	
19 MAR 2021	MOH'S SURGERY	Adverse Event	

US3432202

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:02

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3432202

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:02

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 ☐

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	28/SEP/2020 08:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	20/OCT/2020 16:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	30/OCT/2020 15:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 16:47
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

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 01:59:00

Generated On: 09 Jun 2021 17:34:02

SAEID	USA-US078-2020-MRNA-1273-P301000003
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)	6
Date of submission (Pre-filled from custom function)	26/JAN/2021 11:34
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

Audit

US3432202 (Prod: Brigham and Womens Hospital)

US3432202

Form: Participant Creation

Generated On: 09 Jun 2021 17:34:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:59:02
User entered 'US3432202'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 18:04:31

US3432202

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:07

US3432202

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:33

US3432202

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[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 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:07

US3432202

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'SCRN'	System	19 Aug 2020 18:42:07

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:34

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '77'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'YEARS'	System	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '77'	System	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Male (M)'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:02

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:32

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Aug 2020'	System	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2020'	System	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Amendment 2 (2)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:25

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:33

US3432202

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'I'	System	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:41:39

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:46:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:46:19
Data point term sent to Coder	System	19 Aug 2020 20:45:03
User entered 'Diabetes mellitus'	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'un UNK 2010'	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:45:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 20:45:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:45:08
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:44:58
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
Signature has been broken.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2010'	System	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2010'	System	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:44:58

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:09
User entered 'Anxiety'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'un UNK 2005'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2005'	System	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2005'	System	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:46:30

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 01:24:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 01:24:42
Data point term sent to Coder	System	15 Mar 2021 20:02:06
Coding entries removed.	Monica Feeley (b) (4)	15 Mar 2021 20:01:50
Signature has been broken.	Monica Feeley (b) (4)	15 Mar 2021 20:01:50
User entered 'HIGH CHOLESTEROL (HLD)' reason for change: Data Entry Error	Monica Feeley (b) (4)	15 Mar 2021 20:01:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:08
User entered 'High cholesterol'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'un UNK 2010'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2010'	System	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2010'	System	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:46:48

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:48:07
Data point term sent to Coder	System	19 Aug 2020 20:47:09
User entered 'Duodenal ulcer'	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'un UNK 2019'	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:47:04

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 12:20:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 12:20:35
Data point term sent to Coder	System	19 Oct 2020 18:49:25
Coding entries removed.	Monica Feeley (b) (4)	19 Oct 2020 18:49:03
User entered 'Daily HEADACHES' reason for change: Data Entry Error	Monica Feeley (b) (4)	19 Oct 2020 18:49:03
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:50:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:50:06
Data point term sent to Coder	System	19 Aug 2020 20:49:11
User entered 'occasional headaches'	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'un UNK 2019'	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Aug 2020 20:48:47

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Chronic fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 06:15:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 06:15:45
Data point term sent to Coder	System	02 Sep 2020 00:25:31
User entered 'chronic fatigue (being followed by physician)'	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'UN Nov 2019'	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Nov 2019'	System	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	02 Sep 2020 00:24:42

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
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: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 05:52:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 05:52:53
Data point term sent to Coder	System	16 Sep 2020 21:52:24
User entered 'Neck pain { being followed by MD}'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'UN May 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'May 2020'	System	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2020'	System	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:07

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Gait disturbances, PT: Gait disturbance, LLT: Gait instability - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:54:43
Data point term sent to Coder	System	16 Sep 2020 21:53:26
User entered 'gait instability'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'UN UNK 2017'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2017'	System	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2017'	System	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:41

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Choreiform movements, PT: Chorea, LLT: Chorea - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:54:43
Data point term sent to Coder	System	16 Sep 2020 21:53:26
User entered 'chorea'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'UN UNK 2017'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2017'	System	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2017'	System	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	16 Sep 2020 21:52:58

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 18:51:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 18:51:24
Data point term sent to Coder	System	19 Oct 2020 18:50:27
User entered 'Hypertension'	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'UN Jan 2020'	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Monica Feeley (b) (4)	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2020'	System	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2020'	System	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	19 Oct 2020 18:49:27

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
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)	20 Nov 2020 21:24:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 21:24:07
Data point term sent to Coder	System	20 Nov 2020 21:23:42
User entered 'Depression'	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'I'	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Monica Feeley (b) (4)	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	20 Nov 2020 21:23:04

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 18:48:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 18:48:46
Data point term sent to Coder	System	24 Mar 2021 18:47:17
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 18:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 18:46:25
User entered 'Vertigo' reason for change: Data Entry Error	Monica Feeley (b) (4)	24 Mar 2021 18:46:25
Data point term sent to Coder	System	24 Mar 2021 18:46:16
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
Data point term sent to Coder	System	15 Mar 2021 20:02:06
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 20:01:16
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	15 Mar 2021 20:01:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 18:35:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 18:35:31
Data point term sent to Coder	System	15 Mar 2021 18:35:13
User entered 'Basal Cell Carcinoma'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	24 Mar 2021 18:46:25
User entered 'UN UNK 2019' reason for change: Data Entry Error	Monica Feeley (b) (4)	24 Mar 2021 18:46:25
DataPoint activated with code reason code Data required.	(b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 20:01:34
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	15 Mar 2021 20:01:16
User entered empty; reason for change Data Entry Error	System	15 Mar 2021 20:01:16
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	Monica Feeley (b) (4)	15 Mar 2021 20:01:16
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 18:40:17
User entered '20 Feb 2021' reason for change: Data Entry Error	System	15 Mar 2021 18:40:17
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	Tenaizus Woods (b) (4)	15 Mar 2021 18:40:17
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 18:39:29
User entered '02 Feb 2021' reason for change: Data Entry Error	System	15 Mar 2021 18:39:29
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	Tenaizus Woods (b) (4)	15 Mar 2021 18:39:29
User entered 'un UNK 2021'	(b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 18:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 18:46:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	24 Mar 2021 18:46:25
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 20:01:16
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	15 Mar 2021 20:01:16
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:10:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	24 Mar 2021 18:46:25
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	(b) (4)	15 Mar 2021 20:01:34
User entered empty.	System	15 Mar 2021 20:01:16
User entered 'Feb 2021'	System	15 Mar 2021 18:39:29
User entered 'Jan 2021'	System	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	24 Mar 2021 18:46:25
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	(b) (4)	15 Mar 2021 20:01:34
User entered empty.	System	15 Mar 2021 20:01:16
User entered '2021'	System	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
	(b) (4)	
User entered empty.	System	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	24 Mar 2021 18:45:28
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Monica Feeley (b) (4)	15 Mar 2021 20:01:34
	(b) (4)	
User entered empty.	System	15 Mar 2021 18:34:57

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system aneurysms and dissections, PT: Vertebral artery dissection, LLT: Vertebral artery dissection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 11:14:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 11:14:36
Data point term sent to Coder	System	24 Mar 2021 18:47:18
User entered 'L vertebral artery dissection'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'UN UNK 2019'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'UN UNK 2019'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:17:04
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	24 Mar 2021 18:46:56

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 12:31:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 12:31:02
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 12:30:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 12:30:13
Data point term sent to Coder	System	29 Mar 2021 12:30:13
User closed query 'DM-Coding: for term AKI, Please expand the reported abbreviation AKI, entering the full text as the reported term.' (Site from System).	System	29 Mar 2021 12:29:50
Query 'DM-Coding: for term AKI, Please expand the reported abbreviation AKI, entering the full text as the reported term.' answered with 'full term, acute kidney injury, written out' (Site from System).	Bruce Bausk (b) (4)	29 Mar 2021 12:29:50
Data point term sent to Coder	System	29 Mar 2021 12:29:12
User entered 'Acute Kidney Injury' reason for change: Data Entry Error	Bruce Bausk (b) (4)	29 Mar 2021 12:28:57
User opened query 'DM-Coding: for term AKI, Please expand the reported abbreviation AKI, entering the full text as the reported term.' (Site from System).	Coder Import (b) (4)	29 Mar 2021 12:20:03
Data point term sent to Coder	System	24 Mar 2021 18:48:20
User entered 'AKI'	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '28 Jan 2019'	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:59
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'I'	Monica Feeley (b) (4)	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Jan 2019'	System	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2019'	System	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:47:41

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Corneal infections, oedemas and inflammations, PT: Exposure keratitis, LLT: Exposure keratoconjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:03:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:03:10
Data point term sent to Coder	System	24 Mar 2021 18:53:31
User entered 'Exposure keratoconjunctivitis L eye'	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'I'	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'I'	Monica Feeley (b) (4)	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered empty.	System	24 Mar 2021 18:53:28

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Lid, lash and lacrimal structural disorders, PT: Eyelid retraction, LLT: Eyelid retraction - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:05:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:05:04
Data point term sent to Coder	System	24 Mar 2021 18:54:42
User entered 'Eyelid retraction L eye'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '03 Oct 2016'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '03 Oct 2016'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:10
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Oct 2016'	System	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2016'	System	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'Oct 2016'	System	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '2016'	System	24 Mar 2021 18:53:50

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:43'	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered '19 Aug 2020 14:43'	System	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '174' cm	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '81.7' kg	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
Amendment Manager: User entered '26.98507'	System	17 Sep 2020 00:14:33
User entered '27.0'	System	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'kg/m2'	System	19 Aug 2020 20:49:32
DataPoint set to visible.	System	19 Aug 2020 18:42:29

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:26:00
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 20:49:56
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'bpm'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'breaths/min'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'mmHg'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 20:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 20:49:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 20:49:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 20:49:32
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User entered 'mmHg'	System	19 Aug 2020 20:49:48
User entered empty.	System	19 Aug 2020 20:49:32

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04

US3432202

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04

US3432202

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:43:39

US3432202

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 11:22:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		16 Sep 2020 21:44:20
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:43:39

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'retired'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:34:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:50:35

US3432202

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:40

US3432202

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:40

US3432202

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	19 Aug 2020 18:42:40

US3432202

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'VISIT1'	System	19 Aug 2020 18:42:40

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:38:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:38:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 18:04:46
User entered '187067' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:46

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:51:07

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:51:07

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:51:07

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:51:07

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:51:07

US3432202

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:02

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 18:53:58
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:44

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:43'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '19 Aug 2020 14:43'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '37.2' C	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '98'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'bpm'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '20'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'breaths/min'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '136'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '70'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:26:23
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).		19 Aug 2020 20:52:58
User entered '16:09'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '19 Aug 2020 16:09'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '37.4' C	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '95'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'bpm'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '15'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'breaths/min'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '125'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '74'	Bruce Bausk (b) (4)	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	19 Aug 2020 20:52:58

US3432202

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:57:54

US3432202

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:57:54

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '15:39'	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '19 Aug 2020 15:39'	System	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4)	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'ONCE'	System	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:04:44

US3432202

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:10

US3432202

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:10

US3432202

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:55'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:10

US3432202

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '19 Aug 2020 14:55'	System	19 Aug 2020 20:58:10

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '19 Aug 2020'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '15:02'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '19 Aug 2020 15:02'	System	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bruce Bausk (b) (4) (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered empty.	System	19 Aug 2020 20:58:25

US3432202

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:29

US3432202

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	19 Aug 2020 20:58:29

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered 'Yes (Y)'	System	19 Aug 2020 20:10:41

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered '99.4'	System	19 Aug 2020 20:10:41

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered 'No (N)'	System	19 Aug 2020 20:10:41

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:10:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bc296eaa-262c-4add-9dda-664322731362'	System	19 Aug 2020 20:10:41
User entered '19 Aug 2020 16:10'	System	19 Aug 2020 20:10:41

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:05:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered 'Yes (Y)'	System	20 Aug 2020 00:06:45

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f' User entered '98.7'	System	20 Aug 2020 00:06:45
	System	20 Aug 2020 00:06:45

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered 'No (N)'	System	20 Aug 2020 00:06:45

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:06:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2506b62c-3beb-4fad-bab4-f4573f6a431f'	System	20 Aug 2020 00:06:45
User entered '19 Aug 2020 20:06'	System	20 Aug 2020 00:06:45

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered 'Yes (Y)'	System	21 Aug 2020 02:02:52

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered '99.2'	System	21 Aug 2020 02:02:52

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered 'No (N)'	System	21 Aug 2020 02:02:52

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:02:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '12f2eff2-b6be-481d-8476-79353dda8449'	System	21 Aug 2020 02:02:52
User entered '20 Aug 2020 22:02'	System	21 Aug 2020 02:02:52

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered 'Yes (Y)'	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '99.7'	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:07:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered 'Yes (Y)'	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
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 'medication recorded in log after safety call' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 19:51:10
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 (0e44f629885d0df0)', Time: '2020-08-21T21:08:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	Monica Feeley (b) (4)	26 Aug 2020 12:59:31
User entered '1'	System	22 Aug 2020 01:08:32
	System	22 Aug 2020 01:08:32
	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '0'	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2660c800-c9e7-49df-ba48-1e460e8a29d0'	System	22 Aug 2020 01:08:32
User entered '21 Aug 2020 21:08'	System	22 Aug 2020 01:08:32

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered 'Yes (Y)'	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '98.7'	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:07:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered 'Yes (Y)'	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
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 'medication recorded after safety call' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 19:51:15
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).	Monica Feeley (b) (4)	26 Aug 2020 13:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	(b) (4)	
User entered '1'	System	23 Aug 2020 00:09:21
	System	23 Aug 2020 00:09:21
	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '0'	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '857af27d-8e62-413e-8431-98401481d656'	System	23 Aug 2020 00:09:21
User entered '22 Aug 2020 20:08'	System	23 Aug 2020 00:09:21

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered 'Yes (Y)'	System	23 Aug 2020 23:03:57

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d' User entered '98.4'	System	23 Aug 2020 23:03:57
	System	23 Aug 2020 23:03:57

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered 'No (N)'	System	23 Aug 2020 23:03:57

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:03:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1aa04b3-7736-40f6-b45d-5946adc9703d'	System	23 Aug 2020 23:03:57
User entered '23 Aug 2020 19:03'	System	23 Aug 2020 23:03:57

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered 'Yes (Y)'	System	25 Aug 2020 04:04:00

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f' User entered '98.9'	System	25 Aug 2020 04:04:00
	System	25 Aug 2020 04:04:00

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered 'No (N)'	System	25 Aug 2020 04:04:00

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:03:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f184329c-e3f6-4c86-8735-fa31bc05878f'	System	25 Aug 2020 04:04:00
User entered '25 Aug 2020 00:03'	System	25 Aug 2020 04:04:00

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:27:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered 'Yes (Y)'	System	26 Aug 2020 02:28:15

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:27:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f' User entered '96.9'	System	26 Aug 2020 02:28:15
	System	26 Aug 2020 02:28:15

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered 'No (N)'	System	26 Aug 2020 02:28:15

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe323b35-c6e5-4f2a-86e3-4226c467028f'	System	26 Aug 2020 02:28:15
User entered '25 Aug 2020 22:28'	System	26 Aug 2020 02:28:15

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'None (1)'	System	19 Aug 2020 20:13:39

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'No (N)'	System	19 Aug 2020 20:13:39

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'No (N)'	System	19 Aug 2020 20:13:39

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered 'None (1)'	System	19 Aug 2020 20:13:39

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8da26fe2-5bf8-435c-980d-96e56d0b168b'	System	19 Aug 2020 20:13:39
User entered '19 Aug 2020 16:13'	System	19 Aug 2020 20:13:39

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'None (1)'	System	20 Aug 2020 00:07:50

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'No (N)'	System	20 Aug 2020 00:07:50

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'No (N)'	System	20 Aug 2020 00:07:50

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered 'None (1)'	System	20 Aug 2020 00:07:50

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:07:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6e2cb261-7370-449d-978f-3c3edcfa5e8e'	System	20 Aug 2020 00:07:50
User entered '19 Aug 2020 20:07'	System	20 Aug 2020 00:07:50

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'None (1)'	System	21 Aug 2020 02:04:01

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'No (N)'	System	21 Aug 2020 02:04:01

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'No (N)'	System	21 Aug 2020 02:04:01

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered 'None (1)'	System	21 Aug 2020 02:04:01

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:03:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a6727e02-aaca-42bb-9079-eb15a84aa2e7'	System	21 Aug 2020 02:04:01
User entered '20 Aug 2020 22:03'	System	21 Aug 2020 02:04:01

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'None (1)'	System	22 Aug 2020 01:09:51

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:08:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'No (N)'	System	22 Aug 2020 01:09:51

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'No (N)'	System	22 Aug 2020 01:09:51

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered 'None (1)'	System	22 Aug 2020 01:09:51

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:09:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '1791fa1f-04e8-440b-a6b4-37a2afa846f9'	System	22 Aug 2020 01:09:51
User entered '21 Aug 2020 21:09'	System	22 Aug 2020 01:09:51

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'None (1)'	System	23 Aug 2020 00:09:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'No (N)'	System	23 Aug 2020 00:09:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'No (N)'	System	23 Aug 2020 00:09:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:44', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered 'None (1)'	System	23 Aug 2020 00:09:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:08:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6836f12b-be75-4f70-bda5-e69bc5ab9fd8'	System	23 Aug 2020 00:09:47
User entered '22 Aug 2020 20:08'	System	23 Aug 2020 00:09:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'None (1)'	System	23 Aug 2020 23:04:41

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'No (N)'	System	23 Aug 2020 23:04:41

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'No (N)'	System	23 Aug 2020 23:04:41

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered 'None (1)'	System	23 Aug 2020 23:04:41

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:04:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '14773892-24a1-4e95-bbce-0861969ab082'	System	23 Aug 2020 23:04:41
User entered '23 Aug 2020 19:04'	System	23 Aug 2020 23:04:41

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'None (1)'	System	25 Aug 2020 04:04:32

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'No (N)'	System	25 Aug 2020 04:04:32

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'No (N)'	System	25 Aug 2020 04:04:32

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered 'None (1)'	System	25 Aug 2020 04:04:32

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8f0ea925-8b82-4159-8008-6b86a16b6ed3'	System	25 Aug 2020 04:04:32
User entered '25 Aug 2020 00:04'	System	25 Aug 2020 04:04:32

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'None (1)'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'No (N)'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'No (N)'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered 'None (1)'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:28:44', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd49671aa-482c-49cf-a4c1-cc54b17c59a1'	System	26 Aug 2020 02:28:47
User entered '25 Aug 2020 22:28'	System	26 Aug 2020 02:28:47

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:13:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'None (0)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered 'No (N)'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T16:14:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd039f43d-c7df-4fdd-87e4-51c2dda5d7f1'	System	19 Aug 2020 20:15:08
User entered '19 Aug 2020 16:14'	System	19 Aug 2020 20:15:08

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 15:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 18:29'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:19', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'None (0)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:08:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered 'No (N)'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-19T20:09:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '21dda515-7393-4b2c-bdb0-25608f0efa0c'	System	20 Aug 2020 00:09:12
User entered '19 Aug 2020 20:09'	System	20 Aug 2020 00:09:12

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Aug 2020 19:24'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 2'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'None (0)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:04:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered 'Yes (Y)'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-20T22:05:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cb4c0c86-539b-417f-bd05-662a4086379c'	System	21 Aug 2020 02:05:24
User entered '20 Aug 2020 22:05'	System	21 Aug 2020 02:05:24

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 3'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'None (0)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:10:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered 'Yes (Y)'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-21T21:11:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b81352cc-ccc6-4343-af77-5b4f9630140c'	System	22 Aug 2020 01:11:16
User entered '21 Aug 2020 21:11'	System	22 Aug 2020 01:11:16

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 4'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'None (0)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:09:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered 'No (N)'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-22T20:10:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8bda09da-a3b7-47f6-a9cc-934951dba1a7'	System	23 Aug 2020 00:10:13
User entered '22 Aug 2020 20:10'	System	23 Aug 2020 00:10:13

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 5'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'None (0)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered 'No (N)'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-23T19:05:37', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fcb255f1-9380-4d06-a2cc-ac5dc71cad55'	System	23 Aug 2020 23:05:40
User entered '23 Aug 2020 19:05'	System	23 Aug 2020 23:05:40

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 6'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No interference with activity (1)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No interference with activity (1)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:04:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'None (0)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered 'No (N)'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T00:05:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '23d916f2-6f67-45d7-9270-e41246d22428'	System	25 Aug 2020 04:05:38
User entered '25 Aug 2020 00:05'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 7'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:22', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'None (0)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered 'No (N)'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-25T22:29:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5b2bbc6e-8a78-4fec-8a06-5ce82de9e855'	System	26 Aug 2020 02:29:53
User entered '25 Aug 2020 22:29'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd467e7b9-2f7a-43dd-bc1e-d00f2420c8a7'	System	27 Aug 2020 02:14:33
User entered 'None (0)'	System	27 Aug 2020 02:14:33

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd467e7b9-2f7a-43dd-bc1e-d00f2420c8a7'	System	27 Aug 2020 02:14:33
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:14:33

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '49d4db94-36f7-4078-94bc-21521f594dbf'	System	27 Aug 2020 02:14:48
User entered 'No interference with activity (1)'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '49d4db94-36f7-4078-94bc-21521f594dbf'	System	27 Aug 2020 02:14:48
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	26 Aug 2020 02:29:53
User entered 'Day 9'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'aa5642a1-5e58-42fe-a319-dbdd4effb9af'	System	27 Aug 2020 16:01:14
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'aa5642a1-5e58-42fe-a319-dbdd4effb9af'	System	27 Aug 2020 16:01:14
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	27 Aug 2020 02:14:48
User entered 'Day 10'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6f257b4d-2560-4d12-b469-88cd75b76a26'	System	29 Aug 2020 01:12:13
User entered 'Some interference with activity (2)'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6f257b4d-2560-4d12-b469-88cd75b76a26'	System	29 Aug 2020 01:12:13
User entered '28 Aug 2020 21:12'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	27 Aug 2020 16:01:14
User entered 'Day 11'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '77563e9f-47e6-4afc-8cd8-0cece1bad412'	System	29 Aug 2020 16:57:34
User entered 'No interference with activity (1)'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '77563e9f-47e6-4afc-8cd8-0cece1bad412'	System	29 Aug 2020 16:57:34
User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	29 Aug 2020 01:12:13
User entered 'Day 12'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '758887af-91df-487b-b3fd-388e22a55cdb'	System	30 Aug 2020 23:53:07
User entered 'No interference with activity (1)'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '758887af-91df-487b-b3fd-388e22a55cdb'	System	30 Aug 2020 23:53:07
User entered '30 Aug 2020 19:53'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	29 Aug 2020 16:57:34
User entered 'Day 13'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4f18423a-7b82-4706-af14-09672390c2d0'	System	31 Aug 2020 19:40:42
User entered 'No interference with activity (1)'	System	31 Aug 2020 19:40:42

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4f18423a-7b82-4706-af14-09672390c2d0'	System	31 Aug 2020 19:40:42
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 19:40:42

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	30 Aug 2020 23:53:07
User entered 'Day 14'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '80ab8166-62af-4142-8646-2ab1075a79ce'	System	01 Sep 2020 16:26:07
User entered 'None (0)'	System	01 Sep 2020 16:26:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '80ab8166-62af-4142-8646-2ab1075a79ce'	System	01 Sep 2020 16:26:07
User entered '01 Sep 2020 12:26'	System	01 Sep 2020 16:26:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	25 Aug 2020 04:05:38
User entered 'Day 8'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd987f8ec-9815-438c-b47c-1e2faef9d21e'	System	27 Aug 2020 02:15:07
User entered 'No (N)'	System	27 Aug 2020 02:15:07

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-26T22:14:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd987f8ec-9815-438c-b47c-1e2faef9d21e'	System	27 Aug 2020 02:15:07
User entered '26 Aug 2020 22:14'	System	27 Aug 2020 02:15:07

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 04:05:38

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
Data entry locked.	System	26 Aug 2020 02:29:53
User entered 'Day 9'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '441e303f-1c8f-4911-bcd9-1a1b3067b702'	System	27 Aug 2020 16:01:27
User entered 'No (N)'	System	27 Aug 2020 16:01:27
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-27T12:01:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '441e303f-1c8f-4911-bcd9-1a1b3067b702'	System	27 Aug 2020 16:01:27
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:27
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
DataPoint Activated.	System	27 Aug 2020 02:14:48
DataPoint Inactivated.	System	27 Aug 2020 02:14:33
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:29:53

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	27 Aug 2020 02:14:48
User entered 'Day 10'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6984c51a-52fd-43e4-8524-20916b9cb7c0'	System	29 Aug 2020 01:12:23
User entered 'No (N)'	System	29 Aug 2020 01:12:23

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-28T21:12:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6984c51a-52fd-43e4-8524-20916b9cb7c0'	System	29 Aug 2020 01:12:23
User entered '28 Aug 2020 21:12'	System	29 Aug 2020 01:12:23

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:14:48

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	27 Aug 2020 16:01:14
User entered 'Day 11'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e068e47d-256c-4ddc-814d-2ef432ef1942'	System	29 Aug 2020 16:57:45
User entered 'No (N)'	System	29 Aug 2020 16:57:45

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-29T12:57:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e068e47d-256c-4ddc-814d-2ef432ef1942'	System	29 Aug 2020 16:57:45
User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:45

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:14

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	29 Aug 2020 01:12:13
User entered 'Day 12'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e19a6529-07dc-471b-b982-f08321ecfa89'	System	30 Aug 2020 23:53:23
User entered 'No (N)'	System	30 Aug 2020 23:53:23

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-30T19:53:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e19a6529-07dc-471b-b982-f08321ecfa89'	System	30 Aug 2020 23:53:23
User entered '30 Aug 2020 19:53'	System	30 Aug 2020 23:53:23

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:12:13

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	29 Aug 2020 16:57:34
User entered 'Day 13'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0abcd49e-8080-4316-889b-33cec902d715'	System	31 Aug 2020 19:40:54
User entered 'No (N)'	System	31 Aug 2020 19:40:54

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-08-31T15:40:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0abcd49e-8080-4316-889b-33cec902d715'	System	31 Aug 2020 19:40:54
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 19:40:54

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 16:57:34

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	30 Aug 2020 23:53:07
User entered 'Day 14'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:12', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '62e2a789-5573-49a6-8434-cdbf9cff7d55'	System	01 Sep 2020 16:26:19
User entered 'No (N)'	System	01 Sep 2020 16:26:19

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-01T12:26:16', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '62e2a789-5573-49a6-8434-cdbf9cff7d55'	System	01 Sep 2020 16:26:19
User entered '01 Sep 2020 12:26'	System	01 Sep 2020 16:26:19

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:53:07

US3432202

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:53:07

US3432202

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

US3432202

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

US3432202

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

US3432202

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:56:39

US3432202

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:11

US3432202

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	26 Aug 2020 21:58:11

US3432202

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

US3432202

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '02 Sep 2020' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	10 Nov 2020 15:09:39
User entered '2 Sep 2020'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

US3432202

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

US3432202

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:26

US3432202

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 21:41:30

US3432202

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	02 Sep 2020 21:41:30

US3432202

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Megan Powell (b) (4)	09 Sep 2020 23:48:51

US3432202

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '09 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:13:05
User entered '9 Sep 2020'	Megan Powell (b) (4)	09 Sep 2020 23:48:51

US3432202

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	Megan Powell (b) (4)	09 Sep 2020 23:48:51

US3432202

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Megan Powell (b) (4)	09 Sep 2020 23:48:51

US3432202

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 20:02:49

US3432202

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	16 Sep 2020 20:02:49

US3432202

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:44:20

US3432202

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:44:20

US3432202

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:44:20

US3432202

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'VISIT2'	System	16 Sep 2020 21:44:20

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Pre-Dose (PREDOSE)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '13:55'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '16 Sep 2020 13:55'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '37.1' C	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '95'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'bpm'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '18'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'breaths/min'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '132'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '061'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Post-Dose (POSTDOSE)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16:00'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '16 Sep 2020 16:00'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '97.1' F	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Other (Other)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'IR'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '096'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'bpm'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'breaths/min'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '138'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '067'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	16 Sep 2020 21:46:09

US3432202

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:32

US3432202

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:46:32

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '15:24'	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '16 Sep 2020 15:24'	System	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Left Arm (LEFT ARM)'	Xhoi Mitre (b) (4)	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'ONCE'	System	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 20:03:26

US3432202

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:05

US3432202

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:05

US3432202

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:20'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:05

US3432202

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '16 Sep 2020 14:20'	System	16 Sep 2020 21:50:05

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '16 Sep 2020'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:22'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '16 Sep 2020 14:22'	System	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Xhoi Mitre (b) (4) (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered empty.	System	16 Sep 2020 21:50:21

US3432202

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	16 Sep 2020 21:50:27

US3432202

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '1'	System	16 Sep 2020 21:50:27

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered 'Yes (Y)'	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '97.1'	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered 'Yes (Y)'	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
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 'yes' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 07:33:27
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).	Monica Feeley (b) (4)	10 Nov 2020 22:38:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	(b) (4)	
User entered '1'	System	16 Sep 2020 20:09:12
	System	16 Sep 2020 20:09:12
	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:08:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '0'	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ee7e7883-f298-41e3-95bf-7194ed0b08a5'	System	16 Sep 2020 20:09:12
User entered '16 Sep 2020 16:09'	System	16 Sep 2020 20:09:12

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:47:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dff4308'	System	17 Sep 2020 01:48:16
User entered 'Yes (Y)'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:47:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dff4308'	System	17 Sep 2020 01:48:16
User entered '99.1'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dff4308'	System	17 Sep 2020 01:48:16
User entered 'Yes (Y)'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
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 'yes' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 07:33:32
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).	Monica Feeley (b) (4)	10 Nov 2020 22:39:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dfff4308'	(b) (4)	
User entered '1'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dff4308'	System	17 Sep 2020 01:48:16
User entered '0'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'f54988c7-baf6-488d-840f-4ef7dff4308'	System	17 Sep 2020 01:48:16
User entered '16 Sep 2020 21:48'	System	17 Sep 2020 01:48:16

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered 'Yes (Y)'	System	17 Sep 2020 16:04:03

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered '98.6'	System	17 Sep 2020 16:04:03

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered 'No (N)'	System	17 Sep 2020 16:04:03

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'd84ea7ff-33c9-4339-9cf7-083ad7ce49a2'	System	17 Sep 2020 16:04:03
User entered '17 Sep 2020 12:02'	System	17 Sep 2020 16:04:03

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered 'Yes (Y)'	System	19 Sep 2020 04:08:04

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered '96.6'	System	19 Sep 2020 04:08:04

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:07:48', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered 'No (N)'	System	19 Sep 2020 04:08:04

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d443e5c-4d1b-48d5-be7e-e91e902f2b72'	System	19 Sep 2020 04:08:04
User entered '19 Sep 2020 00:08'	System	19 Sep 2020 04:08:04

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered 'Yes (Y)'	System	20 Sep 2020 02:39:09

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf' User entered '98.0'	System	20 Sep 2020 02:39:09
	System	20 Sep 2020 02:39:09

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:38:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered 'No (N)'	System	20 Sep 2020 02:39:09

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:39:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7d5a5232-c675-492b-9747-e0b73d808ccf'	System	20 Sep 2020 02:39:09
User entered '19 Sep 2020 22:39'	System	20 Sep 2020 02:39:09

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:10:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered 'Yes (Y)'	System	21 Sep 2020 02:11:31

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:10:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered '97.4'	System	21 Sep 2020 02:11:31

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered 'No (N)'	System	21 Sep 2020 02:11:31

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '74b4e3ef-3216-4292-b796-c7ea9b28b4d9'	System	21 Sep 2020 02:11:31
User entered '20 Sep 2020 22:11'	System	21 Sep 2020 02:11:31

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:19:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered 'Yes (Y)'	System	22 Sep 2020 20:20:52

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017' User entered '97.5'	System	22 Sep 2020 20:20:52
	System	22 Sep 2020 20:20:52

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered 'No (N)'	System	22 Sep 2020 20:20:52

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T16:20:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e9bb1969-4b20-44fc-923a-3d17a8511017'	System	22 Sep 2020 20:20:52
User entered '22 Sep 2020 16:20'	System	22 Sep 2020 20:20:52

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'None (1)'	System	16 Sep 2020 20:10:12

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'No (N)'	System	16 Sep 2020 20:10:12

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'No (N)'	System	16 Sep 2020 20:10:12

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered 'None (1)'	System	16 Sep 2020 20:10:12

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'a1995a12-27a7-4e92-9c60-627408add54a'	System	16 Sep 2020 20:10:12
User entered '16 Sep 2020 16:10'	System	16 Sep 2020 20:10:12

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'None (1)'	System	17 Sep 2020 01:48:53

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'No (N)'	System	17 Sep 2020 01:48:53

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'No (N)'	System	17 Sep 2020 01:48:53

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered 'None (1)'	System	17 Sep 2020 01:48:53

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:48:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '7a5beaea-5ac8-4860-a06c-14e1328ec76f'	System	17 Sep 2020 01:48:53
User entered '16 Sep 2020 21:48'	System	17 Sep 2020 01:48:53

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:53', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'None (1)'	System	17 Sep 2020 16:04:45

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:02:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'No (N)'	System	17 Sep 2020 16:04:45

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'No (N)'	System	17 Sep 2020 16:04:45

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered 'None (1)'	System	17 Sep 2020 16:04:45

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c290609e-c8d4-4c29-85be-9d702a6080e2'	System	17 Sep 2020 16:04:45
User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:45

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'None (1)'	System	19 Sep 2020 04:09:11

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'No (N)'	System	19 Sep 2020 04:09:11

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:43', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'No (N)'	System	19 Sep 2020 04:09:11

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:08:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered 'None (1)'	System	19 Sep 2020 04:09:11

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'c7023014-6981-4633-b8ad-0a061233b38a'	System	19 Sep 2020 04:09:11
User entered '19 Sep 2020 00:09'	System	19 Sep 2020 04:09:11

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'None (1)'	System	20 Sep 2020 02:40:44

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'No (N)'	System	20 Sep 2020 02:40:44

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'No (N)'	System	20 Sep 2020 02:40:44

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered 'None (1)'	System	20 Sep 2020 02:40:44

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'cba37acd-c61c-4044-80bc-c874d833633b'	System	20 Sep 2020 02:40:44
User entered '19 Sep 2020 22:40'	System	20 Sep 2020 02:40:44

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'None (1)'	System	21 Sep 2020 02:12:19

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'No (N)'	System	21 Sep 2020 02:12:19

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:11:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'No (N)'	System	21 Sep 2020 02:12:19

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered 'None (1)'	System	21 Sep 2020 02:12:19

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '621b24f6-0a67-485a-824c-815a2dd3ab97'	System	21 Sep 2020 02:12:19
User entered '20 Sep 2020 22:12'	System	21 Sep 2020 02:12:19

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'None (1)'	System	22 Sep 2020 23:55:32

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:10', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'No (N)'	System	22 Sep 2020 23:55:32

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'No (N)'	System	22 Sep 2020 23:55:32

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered 'None (1)'	System	22 Sep 2020 23:55:32

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9c125d19-2cc7-4e1f-8ec8-c4d12c9b099d'	System	22 Sep 2020 23:55:32
User entered '22 Sep 2020 19:55'	System	22 Sep 2020 23:55:32

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:43', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:49', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:53', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:10:57', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'None (0)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:11:03', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered 'No (N)'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T16:11:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6ed42d76-8105-4631-9069-89e37a54dc77'	System	16 Sep 2020 20:11:11
User entered '16 Sep 2020 16:11'	System	16 Sep 2020 20:11:11

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 15:44'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 18:14'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:11', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcbff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:22', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'None (0)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered 'No (N)'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-16T21:49:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '47cc5d14-452f-4a18-9735-fccbcff6b1f0'	System	17 Sep 2020 01:49:37
User entered '16 Sep 2020 21:49'	System	17 Sep 2020 01:49:37

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '16 Sep 2020 19:09'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 2'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:24', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:32', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'None (0)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered 'No (N)'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-17T12:03:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'ed5faf4c-5c07-4eb4-ae28-3b70e3820961'	System	17 Sep 2020 16:05:03
User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:05:03

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 3'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:26', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'None (0)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:09:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered 'No (N)'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T00:10:06', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '76fd99f7-5427-4a30-9214-442e19a6ad9f'	System	19 Sep 2020 04:10:24
User entered '19 Sep 2020 00:10'	System	19 Sep 2020 04:10:24

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 4'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:40:54', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:01', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'None (0)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered 'No (N)'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-19T22:41:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e5e831c1-44fd-4396-829c-f37ca6cda769'	System	20 Sep 2020 02:41:44
User entered '19 Sep 2020 22:41'	System	20 Sep 2020 02:41:44

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 5'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:25', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:12:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'None (0)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered 'No (N)'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-20T22:13:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '8a587aed-e895-44af-b136-26ba8c9e6d65'	System	21 Sep 2020 02:13:22
User entered '20 Sep 2020 22:13'	System	21 Sep 2020 02:13:22

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 6'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	16 Sep 2020 20:03:26
User entered 'Day 7'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:47', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:52', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:55:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'None (0)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:08', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered 'No (N)'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-09-22T19:56:15', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '5fc0298e-44d5-4aeb-ab03-4218ef01441b'	System	22 Sep 2020 23:56:18
User entered '22 Sep 2020 19:56'	System	22 Sep 2020 23:56:18

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 20:03:26

US3432202

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 20:03:26

US3432202

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

US3432202

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '26 Sep 2020'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

US3432202

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

US3432202

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Called Pt. 9/25/2020 at 6:30pm, 9/26/2020 at 11:59am and 2:51pm. Also emailed participant on 9/26/2020.'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:30

US3432202

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Sep 2020 16:24:39

US3432202

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	28 Sep 2020 16:24:39

US3432202

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

US3432202

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '2 Oct 2020'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

US3432202

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

US3432202

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'PT. CALLED ON 29SEP2020 AT 10:22AM, 30SEP2020 AT 6:34PM, AND 01OCT2020 AT 10:55AM AND 4:35PM. PT ALSO EMAILED ON 01OCT2020 AND NO CONTACT WAS MADE.' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:53
User entered 'Pt. called on 29SEP2020 at 10:22am, 30SEP2020 at 6:34pm, and 01OCT2020 at 10:55am and 4:35pm. Pt also emailed on 01OCT2020 and not contact was made.'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:41:38

US3432202

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Oct 2020 13:42:01

US3432202

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	02 Oct 2020 13:42:01

US3432202

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

US3432202

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '8 Oct 2020'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

US3432202

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

US3432202

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'participant called 9:06 and 13:48 on 06OCT2020, 10:30 and 17:39 on 07OCT2020, and 9:44 08OCT2020'	Phoebe Cunningham (b) (4)	13 Oct 2020 13:33:36

US3432202

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Megan Powell (b) (4)	02 Nov 2020 21:00:46

US3432202

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	02 Nov 2020 21:00:46

US3432202

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Megan Powell (b) (4)	02 Nov 2020 21:00:57

US3432202

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 16:50:31
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit 3 was epiped for being out of window' (Site from System).	Megan Powell (b) (4)	02 Nov 2020 21:01:45
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Nov 2020 21:00:57
User entered '2 Nov 2020'	Megan Powell (b) (4)	02 Nov 2020 21:00:57

US3432202

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	02 Nov 2020 21:00:57

US3432202

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'VISIT3'	System	02 Nov 2020 21:00:57

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '2 Nov 2020'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '13:40'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '2 Nov 2020 13:40'	System	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '36.7' C	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '097'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'bpm'	System	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '015'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'breaths/min'	System	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '143'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '068'	Megan Powell (b) (4)	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'mmHg'	System	02 Nov 2020 21:02:42

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50

US3432202

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50

US3432202

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Megan Powell (b) (4)	02 Nov 2020 21:02:49

US3432202

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Megan Powell (b) (4)	02 Nov 2020 21:02:49

US3432202

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Megan Powell (b) (4)	02 Nov 2020 21:03:03

US3432202

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '2 Nov 2020'	Megan Powell (b) (4)	02 Nov 2020 21:03:03

US3432202

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '13:50'	Megan Powell (b) (4)	02 Nov 2020 21:03:03

US3432202

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered '2 Nov 2020 13:50'	System	02 Nov 2020 21:03:03

US3432202

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 14:46:14

US3432202

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	09 Nov 2020 14:46:14

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 64'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:10:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'Yes (Y)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:10:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'No (N)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'No (N)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'Yes (Y)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-21T09:11:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9dea5699-ae19-4496-afca-934ae34d967e'	System	21 Oct 2020 13:11:45
User entered '21 Oct 2020 09:11:34'	System	21 Oct 2020 13:11:45

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 71'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-28T12:16:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered 'No (N)'	System	28 Oct 2020 16:17:09

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-28T12:16:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered 'No (N)'	System	28 Oct 2020 16:17:09

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-10-28T12:16:59', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '3635c62d-f299-453c-bb4e-46bce14d54d3'	System	28 Oct 2020 16:17:09
User entered '28 Oct 2020 12:16:59'	System	28 Oct 2020 16:17:09

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 78'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:54:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'Yes (Y)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:54:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'No (N)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:02', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'No (N)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:13', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'Yes (Y)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:55:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f'	System	04 Nov 2020 16:56:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-04T11:56:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'e346c949-9db5-40fc-990f-2f0de84dc10f' User entered '04 Nov 2020 11:56:04'	System	04 Nov 2020 16:56:15
	System	04 Nov 2020 16:56:15

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered 'Day 92'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'Yes (Y)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:39', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'No (N)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:46', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'No (N)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:16:56', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'Yes (Y)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:17:20', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-16T15:17:29', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '2384f656-5d29-4ca9-88ac-1e7cd7f77b53'	System	16 Nov 2020 20:17:43
User entered '16 Nov 2020 15:17:29'	System	16 Nov 2020 20:17:43

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:04:44

US3432202

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:38
Data entry locked.	System	19 Aug 2020 20:04:44
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:04:44

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-11-22T12:24:07', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered 'No (N)'	System	22 Nov 2020 17:25:00

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-11-22T12:24:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered 'No (N)'	System	22 Nov 2020 17:25:00

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-22T12:24:55', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '86700494-dfcf-4921-8515-07dbdd0ee4a7'	System	22 Nov 2020 17:25:00
User entered '22 Nov 2020 12:24:55'	System	22 Nov 2020 17:25:00

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-11-27T00:20:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b67dae42-4e05-430e-bcfc-a5fcc434a134'	System	27 Nov 2020 05:20:54
User entered 'No (N)'	System	27 Nov 2020 05:20:54

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-11-27T00:20:42', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b67dae42-4e05-430e-bcfc-a5fcc434a134'	System	27 Nov 2020 05:20:54
User entered 'No (N)'	System	27 Nov 2020 05:20:54

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-11-27T00:20:51', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b67dae42-4e05-430e-bcfc-a5fcc434a134'	System	27 Nov 2020 05:20:54
User entered '27 Nov 2020 00:20:51'	System	27 Nov 2020 05:20:54

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-12-06T21:52:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9280f27c-7731-46e2-ac1d-4986bf69bdcf'	System	07 Dec 2020 02:53:46
User entered 'No (N)'	System	07 Dec 2020 02:53:46

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-12-06T21:52:50', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9280f27c-7731-46e2-ac1d-4986bf69bdcf'	System	07 Dec 2020 02:53:46
User entered 'No (N)'	System	07 Dec 2020 02:53:46

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-12-06T21:53:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '9280f27c-7731-46e2-ac1d-4986bf69bdcf' User entered '06 Dec 2020 21:53:09'	System	07 Dec 2020 02:53:46
	System	07 Dec 2020 02:53:46

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-12-13T13:32:14', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '486158ee-1223-40d9-9191-57b1d2ec6282'	System	13 Dec 2020 18:32:28
User entered 'No (N)'	System	13 Dec 2020 18:32:28

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-12-13T13:32:18', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '486158ee-1223-40d9-9191-57b1d2ec6282'	System	13 Dec 2020 18:32:28
User entered 'No (N)'	System	13 Dec 2020 18:32:28

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-12-13T13:32:23', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '486158ee-1223-40d9-9191-57b1d2ec6282'	System	13 Dec 2020 18:32:28
User entered '13 Dec 2020 13:32:23'	System	13 Dec 2020 18:32:28

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-12-18T23:04:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b8f8b9b9-7190-4822-9ba7-abce74ec7a25'	System	19 Dec 2020 04:04:45
User entered 'No (N)'	System	19 Dec 2020 04:04:45

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-12-18T23:04:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b8f8b9b9-7190-4822-9ba7-abce74ec7a25'	System	19 Dec 2020 04:04:45
User entered 'No (N)'	System	19 Dec 2020 04:04:45

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-12-18T23:04:41', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b8f8b9b9-7190-4822-9ba7-abce74ec7a25'	System	19 Dec 2020 04:04:45
User entered '18 Dec 2020 23:04:41'	System	19 Dec 2020 04:04:45

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2020-12-26T18:27:05', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fb810b76-25b4-421d-b670-11eab1c2de7f'	System	26 Dec 2020 23:27:22
User entered 'No (N)'	System	26 Dec 2020 23:27:22

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2020-12-26T18:27:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fb810b76-25b4-421d-b670-11eab1c2de7f'	System	26 Dec 2020 23:27:22
User entered 'No (N)'	System	26 Dec 2020 23:27:22

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2020-12-26T18:27:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fb810b76-25b4-421d-b670-11eab1c2de7f'	System	26 Dec 2020 23:27:22
User entered '26 Dec 2020 18:27:17'	System	26 Dec 2020 23:27:22

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-01-01T20:59:17', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '78c6d89d-45d0-49c1-8ded-d389666b55f5'	System	02 Jan 2021 01:59:37
User entered 'No (N)'	System	02 Jan 2021 01:59:37

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-01-01T20:59:21', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '78c6d89d-45d0-49c1-8ded-d389666b55f5'	System	02 Jan 2021 01:59:37
User entered 'No (N)'	System	02 Jan 2021 01:59:37

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-01-01T20:59:30', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '78c6d89d-45d0-49c1-8ded-d389666b55f5'	System	02 Jan 2021 01:59:37
User entered '01 Jan 2021 20:59:30'	System	02 Jan 2021 01:59:37

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-01-08T22:38:33', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '98a0c48d-4273-4e88-9d0c-91b6041b7678'	System	09 Jan 2021 03:38:51
User entered 'No (N)'	System	09 Jan 2021 03:38:51

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-01-08T22:38:38', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '98a0c48d-4273-4e88-9d0c-91b6041b7678'	System	09 Jan 2021 03:38:51
User entered 'No (N)'	System	09 Jan 2021 03:38:51

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-01-08T22:38:44', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '98a0c48d-4273-4e88-9d0c-91b6041b7678' User entered '08 Jan 2021 22:38:44'	System	09 Jan 2021 03:38:51

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-01-17T17:44:24', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '05aefa42-b14e-42c2-b11a-a2bc4c7058e7'	System	17 Jan 2021 22:44:43
User entered 'No (N)'	System	17 Jan 2021 22:44:43

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-01-17T17:44:28', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '05aefa42-b14e-42c2-b11a-a2bc4c7058e7'	System	17 Jan 2021 22:44:43
User entered 'No (N)'	System	17 Jan 2021 22:44:43

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-01-17T17:44:35', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '05aefa42-b14e-42c2-b11a-a2bc4c7058e7' User entered '17 Jan 2021 17:44:35'	System	17 Jan 2021 22:44:43

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-01-23T20:54:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '73fa74a0-9423-4e59-917b-af37ddcb0d02'	System	24 Jan 2021 01:54:48
User entered 'No (N)'	System	24 Jan 2021 01:54:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-01-23T20:54:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '73fa74a0-9423-4e59-917b-af37ddcb0d02'	System	24 Jan 2021 01:54:48
User entered 'No (N)'	System	24 Jan 2021 01:54:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-01-23T20:54:45', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '73fa74a0-9423-4e59-917b-af37ddcb0d02'	System	24 Jan 2021 01:54:48
User entered '23 Jan 2021 20:54:45'	System	24 Jan 2021 01:54:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-01-30T00:19:34', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '55b5d1c9-499e-4a46-85c6-52bb7247971d'	System	30 Jan 2021 05:20:01
User entered 'No (N)'	System	30 Jan 2021 05:20:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-01-30T00:19:40', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '55b5d1c9-499e-4a46-85c6-52bb7247971d'	System	30 Jan 2021 05:20:01
User entered 'No (N)'	System	30 Jan 2021 05:20:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-01-30T00:19:58', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '55b5d1c9-499e-4a46-85c6-52bb7247971d' User entered '30 Jan 2021 00:19:58'	System	30 Jan 2021 05:20:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-02-05T00:01:27', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bdebba67-d191-4339-beb8-8c89d18e48e8'	System	05 Feb 2021 05:02:08
User entered 'No (N)'	System	05 Feb 2021 05:02:08

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-02-05T00:01:31', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bdebba67-d191-4339-beb8-8c89d18e48e8'	System	05 Feb 2021 05:02:08
User entered 'No (N)'	System	05 Feb 2021 05:02:08

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-02-05T00:01:36', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'bdebba67-d191-4339-beb8-8c89d18e48e8'	System	05 Feb 2021 05:02:08
User entered '05 Feb 2021 00:01:36'	System	05 Feb 2021 05:02:08

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-02-12T19:53:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'db08c9b8-8cac-4eb1-a56d-798163f69eb4'	System	13 Feb 2021 00:53:12
User entered 'No (N)'	System	13 Feb 2021 00:53:12

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-02-12T19:53:04', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'db08c9b8-8cac-4eb1-a56d-798163f69eb4'	System	13 Feb 2021 00:53:12
User entered 'No (N)'	System	13 Feb 2021 00:53:12

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-02-12T19:53:09', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'db08c9b8-8cac-4eb1-a56d-798163f69eb4'	System	13 Feb 2021 00:53:12
User entered '12 Feb 2021 19:53:09'	System	13 Feb 2021 00:53:12

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-03-02T11:22:56-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6beca335-a89a-4f2c-9ee9-854e21fab992'	System	02 Mar 2021 16:23:11
User entered 'No (N)'	System	02 Mar 2021 16:23:11

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-03-02T11:23:00-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6beca335-a89a-4f2c-9ee9-854e21fab992'	System	02 Mar 2021 16:23:11
User entered 'No (N)'	System	02 Mar 2021 16:23:11

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-02T11:23:06-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '6beca335-a89a-4f2c-9ee9-854e21fab992'	System	02 Mar 2021 16:23:11
User entered '02 Mar 2021 11:23:06'	System	02 Mar 2021 16:23:11

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-03-05T00:27:11-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b3c8d284-dcc4-4e29-9760-7f4bc32743d9'	System	05 Mar 2021 05:27:26
User entered 'No (N)'	System	05 Mar 2021 05:27:26

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-03-05T00:27:15-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b3c8d284-dcc4-4e29-9760-7f4bc32743d9'	System	05 Mar 2021 05:27:26
User entered 'No (N)'	System	05 Mar 2021 05:27:26

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-05T00:27:22-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b3c8d284-dcc4-4e29-9760-7f4bc32743d9'	System	05 Mar 2021 05:27:26
User entered '05 Mar 2021 00:27:22'	System	05 Mar 2021 05:27:26

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-03-12T00:01:20-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b4647fde-bc1a-4645-bff6-cc1cce67284b'	System	12 Mar 2021 05:02:14
User entered 'No (N)'	System	12 Mar 2021 05:02:14

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-03-12T00:01:24-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b4647fde-bc1a-4645-bff6-cc1cce67284b'	System	12 Mar 2021 05:02:14
User entered 'No (N)'	System	12 Mar 2021 05:02:14

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-12T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'b4647fde-bc1a-4645-bff6-cc1cce67284b'	System	12 Mar 2021 05:02:14
User entered '12 Mar 2021 00:01:28'	System	12 Mar 2021 05:02:14

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-03-19T00:07:48-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '29ac2879-d3c8-4cac-8576-51b63e0fe25e'	System	19 Mar 2021 04:07:59
User entered 'No (N)'	System	19 Mar 2021 04:07:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-03-19T00:07:52-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '29ac2879-d3c8-4cac-8576-51b63e0fe25e'	System	19 Mar 2021 04:07:59
User entered 'No (N)'	System	19 Mar 2021 04:07:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-19T00:07:56-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '29ac2879-d3c8-4cac-8576-51b63e0fe25e' User entered '19 Mar 2021 00:07:56'	System	19 Mar 2021 04:07:59
	System	19 Mar 2021 04:07:59

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-03-30T22:31:58-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '60dd861d-90b2-402c-91ee-17dbf4181c6d'	System	31 Mar 2021 02:32:10
User entered 'No (N)'	System	31 Mar 2021 02:32:10

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-03-30T22:32:03-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '60dd861d-90b2-402c-91ee-17dbf4181c6d'	System	31 Mar 2021 02:32:10
User entered 'No (N)'	System	31 Mar 2021 02:32:10

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-30T22:32:06-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '60dd861d-90b2-402c-91ee-17dbf4181c6d'	System	31 Mar 2021 02:32:10
User entered '30 Mar 2021 22:32:06'	System	31 Mar 2021 02:32:10

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-04-06T11:59:48-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '623da5e5-ab7a-4535-a928-a768594da292'	System	06 Apr 2021 16:00:02
User entered 'No (N)'	System	06 Apr 2021 16:00:02

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-04-06T11:59:52-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '623da5e5-ab7a-4535-a928-a768594da292'	System	06 Apr 2021 16:00:02
User entered 'No (N)'	System	06 Apr 2021 16:00:02

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-04-06T11:59:57-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '623da5e5-ab7a-4535-a928-a768594da292'	System	06 Apr 2021 16:00:02
User entered '06 Apr 2021 11:59:57'	System	06 Apr 2021 16:00:02

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-04-11T12:04:23-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0ada81dd-dd35-41a4-8dd9-709db8cba52f'	System	11 Apr 2021 16:07:42
User entered 'No (N)'	System	11 Apr 2021 16:07:42

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-04-11T12:04:26-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0ada81dd-dd35-41a4-8dd9-709db8cba52f'	System	11 Apr 2021 16:07:42
User entered 'No (N)'	System	11 Apr 2021 16:07:42

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-04-11T12:04:29-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '0ada81dd-dd35-41a4-8dd9-709db8cba52f' User entered '11 Apr 2021 12:04:29'	System	11 Apr 2021 16:07:42
	System	11 Apr 2021 16:07:42

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-04-18T12:41:50-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe402765-e833-4373-a80c-73c5d76f2a78'	System	18 Apr 2021 16:42:01
User entered 'No (N)'	System	18 Apr 2021 16:42:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-04-18T12:41:54-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe402765-e833-4373-a80c-73c5d76f2a78'	System	18 Apr 2021 16:42:01
User entered 'No (N)'	System	18 Apr 2021 16:42:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-04-18T12:41:57-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'fe402765-e833-4373-a80c-73c5d76f2a78'	System	18 Apr 2021 16:42:01
User entered '18 Apr 2021 12:41:57'	System	18 Apr 2021 16:42:01

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-04-26T00:47:37-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '07e1c8f0-52fc-4e5f-bd4f-814bc2fada42'	System	26 Apr 2021 04:47:48
User entered 'No (N)'	System	26 Apr 2021 04:47:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-04-26T00:47:41-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '07e1c8f0-52fc-4e5f-bd4f-814bc2fada42'	System	26 Apr 2021 04:47:48
User entered 'No (N)'	System	26 Apr 2021 04:47:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-04-26T00:47:44-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '07e1c8f0-52fc-4e5f-bd4f-814bc2fada42' User entered '26 Apr 2021 00:47:44'	System	26 Apr 2021 04:47:48
	System	26 Apr 2021 04:47:48

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[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 (0e44f629885d0df0)', Time: '2021-05-01T20:15:05-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'dfb327f2-64f6-4a0a-bb7f-4f0365661a90'	System	02 May 2021 00:15:20
User entered 'No (N)'	System	02 May 2021 00:15:20

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Have you been exposed to someone with 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 (0e44f629885d0df0)', Time: '2021-05-01T20:15:08-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'dfb327f2-64f6-4a0a-bb7f-4f0365661a90'	System	02 May 2021 00:15:20
User entered 'No (N)'	System	02 May 2021 00:15:20

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-05-01T20:15:11-04:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: 'dfb327f2-64f6-4a0a-bb7f-4f0365661a90'	System	02 May 2021 00:15:20
User entered '01 May 2021 20:15:11'	System	02 May 2021 00:15:20

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:09:57

US3432202

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:57
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:09:57

US3432202

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:02

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 04:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-02T11:23:19-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d49458d-88d9-47bd-a222-6964fdf4d799'	System	02 Mar 2021 16:23:28
User entered 'No (N)'	System	02 Mar 2021 16:23:28

US3432202

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e44f629885d0df0)', Time: '2021-03-02T11:23:25-05:00', User OID: 'PatientReportedOutcome (US3432202)', ODM File OID: '4d49458d-88d9-47bd-a222-6964fdf4d799'	System	02 Mar 2021 16:23:28
User entered '02 Mar 2021 11:23:25'	System	02 Mar 2021 16:23:28

US3432202

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

US3432202

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

US3432202

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 15:29:44

US3432202

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 15:29:44

US3432202

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:29:48

US3432202

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:07:50
User entered 'I'	System	12 Nov 2020 15:29:48

US3432202

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 15:25:23

US3432202

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 15:25:23

US3432202

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Dec 2020 15:25:23

US3432202

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 15:25:23

US3432202

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 15:26:24

US3432202

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User entered 'I'	System	14 Dec 2020 15:26:24

US3432202

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	14 Jan 2021 14:38:24

US3432202

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14 Jan 2021'	Kathleen Garvey (b) (4)	14 Jan 2021 14:38:24

US3432202

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	14 Jan 2021 14:38:24

US3432202

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Kathleen Garvey (b) (4)	14 Jan 2021 14:38:24

US3432202

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	14 Jan 2021 14:38:28

US3432202

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User entered 'I'	System	14 Jan 2021 14:38:28

US3432202

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:31:22

US3432202

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:31:22

US3432202

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 18:31:22

US3432202

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 18:31:22

US3432202

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:31:27

US3432202

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:22
User entered 'I'	System	11 Feb 2021 18:31:27

US3432202

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:23

US3432202

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '15 Mar 2021'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:23

US3432202

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Clinic (Clinic)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:23

US3432202

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'VISIT4'	System	15 Mar 2021 18:32:23

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '15 Mar 2021'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '13:36'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered '15 Mar 2021 13:36'	System	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '36.9' C	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '97'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'bpm'	System	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '12'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'breaths/min'	System	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '130'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'mmHg'	System	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '62'	Bruce Bausk (b) (4)	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'mmHg'	System	29 Mar 2021 20:23:52

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:28

US3432202

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:28

US3432202

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '15 Mar 2021'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '14:15'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered '15 Mar 2021 14:15'	System	15 Mar 2021 18:32:42

US3432202

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:32:45

US3432202

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:42
User entered 'I'	System	15 Mar 2021 18:32:45

US3432202

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:08
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 16:23:57

US3432202

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:08
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 16:23:57

US3432202

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 16:23:57

US3432202

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:08
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 16:23:57

US3432202

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:08
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 16:24:01

US3432202

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:24:01

US3432202

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:13:24

US3432202

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:13:24

US3432202

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[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 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Clinic (Clinic)'	Austin Kim (b) (4)	25 Jan 2021 22:13:24

US3432202

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 22:13:24

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[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 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Bruce Bausk (b) (4)	09 Mar 2021 19:47:59
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:48:38

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Amendment 6 or later (Amendment 6 or later)'	Bruce Bausk (b) (4)	09 Mar 2021 19:47:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:48:38

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Placebo (Placebo)'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Placebo (Placebo)'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Placebo (Placebo)'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	25 Jan 2021 22:13:49

US3432202

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	25 Jan 2021 22:13:49

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered empty.	System	25 Jan 2021 22:20:05
DataPoint set to visible.	System	25 Jan 2021 22:13:49

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered empty.	System	25 Jan 2021 22:20:05
DataPoint set to visible.	System	25 Jan 2021 22:13:49

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User accepted default value 'Pre-Dose (PREDOSE)'	Austin Kim (b) (4) (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:09'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '25 Jan 2021 14:09'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '97.1' F	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '101'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'bpm'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'breaths/min'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '110'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '61'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered missing code ND - Not Done.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered empty.	System	25 Jan 2021 22:20:05
DataPoint set to visible.	System	25 Jan 2021 22:13:49

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User accepted default value 'Post-Dose (POSTDOSE)'	Austin Kim (b) (4) (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '15:23'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '25 Jan 2021 15:23'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '37.0' C	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Oral (Oral)'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '100'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'bpm'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '18'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'breaths/min'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '130'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '63'	Austin Kim (b) (4)	25 Jan 2021 22:20:05

US3432202

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	25 Jan 2021 22:20:05

US3432202

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:20:25

US3432202

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:20:25

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

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 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mRNA-1273'	System	25 Jan 2021 22:20:46
DataPoint set to visible.	System	25 Jan 2021 22:13:49

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:51'	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '25 Jan 2021 14:51'	System	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Left Arm (LEFT ARM)'	Austin Kim (b) (4)	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'ONCE'	System	25 Jan 2021 22:20:46

US3432202

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

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 22:20:46

US3432202

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:21:23

US3432202

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Per Preclarus, received by PPD on 03Feb2021. Accession Number: 1F608EY' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '25 Jan 2021'	(b) (4), (b) (6)	11 Mar 2021 09:14:48
	Bruce Bausk (b) (4)	09 Mar 2021 19:50:41
	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 17:03:45
	Austin Kim (b) (4)	25 Jan 2021 22:21:23
	(b) (4)	

US3432202

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '14:04'	Austin Kim (b) (4)	25 Jan 2021 22:21:23

US3432202

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '25 Jan 2021 14:04'	System	25 Jan 2021 22:21:23

US3432202

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:21:32

US3432202

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '25 Jan 2021'	Austin Kim (b) (4)	25 Jan 2021 22:21:32

US3432202

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '14:07'	Austin Kim (b) (4)	25 Jan 2021 22:21:32

US3432202

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:02

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '25 Jan 2021 14:07'	System	25 Jan 2021 22:21:32

US3432202

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

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	25 Jan 2021 22:21:39

US3432202

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

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	25 Jan 2021 22:21:39

US3432202

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	01 Feb 2021 18:13:43

US3432202

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '1 Feb 2021'	Tenaizus Woods (b) (4)	01 Feb 2021 18:13:43

US3432202

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	01 Feb 2021 18:13:43

US3432202

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Tenaizus Woods (b) (4)	01 Feb 2021 18:13:43

US3432202

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	01 Feb 2021 18:13:46

US3432202

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	01 Feb 2021 18:13:46

US3432202

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '1'	System	01 Feb 2021 18:13:46
DataPoint set to visible.	System	01 Feb 2021 18:13:46

US3432202

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:56:19

US3432202

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '01 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:56:19

US3432202

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Mar 2021 19:56:19

US3432202

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'OLD29'	System	02 Mar 2021 19:56:19

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '01 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '16:24'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '01 Mar 2021 16:24'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '98.4' F	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '094'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'bpm'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '14'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'breaths/min'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '128'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '076'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '01 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '17:26'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '01 Mar 2021 17:26'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '36.9' C	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '087'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'bpm'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '16'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'breaths/min'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '118'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '065'	(b) (4), (b) (6)	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mmHg'	System	02 Mar 2021 19:58:25

US3432202

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:58:36

US3432202

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:58:36

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

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 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'mRNA-1273'	System	02 Mar 2021 19:58:57
DataPoint set to visible.	System	01 Feb 2021 18:13:46

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '16:50'	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered '1 Mar 2021 16:50'	System	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'ONCE'	System	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 19:58:57

US3432202

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:59:02

US3432202

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	02 Mar 2021 19:59:02

US3432202

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	29 Mar 2021 20:29:47

US3432202

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '8 Mar 2021'	Bruce Bausk (b) (4)	29 Mar 2021 20:29:47

US3432202

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Contact Made (CONTACT MADE)'	Bruce Bausk (b) (4)	29 Mar 2021 20:29:47

US3432202

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Bruce Bausk (b) (4)	29 Mar 2021 20:29:47

US3432202

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	29 Mar 2021 20:24:04

US3432202

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:16
User entered 'I'	System	29 Mar 2021 20:24:04

US3432202

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:24:12

US3432202

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '29 Mar 2021'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:24:12

US3432202

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:24:12

US3432202

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 20:24:12

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '29 Mar 2021'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '13:12'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:12'	System	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '98.3' F	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	29 Mar 2021 20:25:13
	(b) (4)	

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered empty.	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '108'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '20'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '125'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '60'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:25:13

US3432202

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Bruce Bausk (b) (4)	29 Mar 2021 20:25:33
	(b) (4)	

US3432202

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered empty.	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:25:33

US3432202

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:27:05

US3432202

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '29 Mar 2021'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:27:05

US3432202

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:40:24
User entered '13:23'	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 20:27:05

US3432202

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:23'	System	29 Mar 2021 20:27:05

US3432202

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:06
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 3; end date: Day 13. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:21:35
User closed query 'Per DM CLR: Safety Follow Up Diary on Day 92 records 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:21:29
Query 'Per DM CLR: Safety Follow Up Diary on Day 92 records 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Confirmed with participant that diary responses of contact with healthcare provider correspond with already captured MAAE of dizziness/cervical stenosis' (Site from DM).	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 14:13:27
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 3; end date: Day 13. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Chronic fatigue already listed as past medical history. This diary fatigue was consistent with baseline medical history.' (Site from DM).	Bruce Bausk (b) (4) (b) (4)	29 Mar 2021 14:04:29

US3432202

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 3; end date: Day 13. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:00:05
User opened query 'Per DM CLR: Safety Follow Up Diary on Day 92 records 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:46:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:30
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:27:03
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:45:56
Query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Will confirm which foot with the participant at next visit and update the AE and con Meds accordingly' (Site from DM).	Megan Powell (b) (4)	21 Oct 2020 22:58:31
User opened query 'Per DM CLR: Please specify the location if Bilateral, Left, or Right. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:33:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Foreign body, LLT: Foreign body - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 07:04:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 07:04:32
Data point term sent to Coder	System	27 Aug 2020 22:33:00
User entered 'Foreign Body in Foot'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:14:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 20:03:26
User entered '20 Aug 2020'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:12:57
Query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' answered with 'unknown start time' (Site from DM).	Monica Feeley (b) (4)	21 Oct 2020 14:31:30
User opened query 'Per CDM: Response noted; However per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 19-AUG-2020 at 15:39, and AE Start date is 20-AUG-2020. Please verify data and update AE Start time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 09:22:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 09:19:30
Query 'Data is required. Please provide.' answered with 'no start time, glass removal from foot' (Site from System).	Xhoi Mitre (b) (4)	27 Aug 2020 22:33:14
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:32:46
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User entered empty.	System	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 21:43:49
User entered 'No (N)' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:49
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 21:43:35
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '2 Sep 2020' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:35
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 09:02:23
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:57
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:43:49
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User entered empty.	System	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '1' reason for change: Per Query Resolution	Jessica Cauley (b) (4)	04 Jan 2021 18:15:15
User entered '0'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'I'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:43:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User entered '0'	System	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20
User entered 'I'	System	27 Aug 2020 22:32:46

US3432202

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:20

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:55:55
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:28
User entered	System	28 Sep 2020 12:53:24
'USA-US078-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 12:53:24

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	12 Feb 2021 22:58:03
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 20:20:18
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'event is as written' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 03:17:18
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:23:31
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:02
User closed query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency"' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:33:49
User closed query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:33:52
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Hypertensive urgency, LLT: Hypertensive urgency - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 12:33:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 12:33:08
Data point term sent to Coder	System	30 Oct 2020 12:32:34
DataPoint Un-verified.	Monica Feeley (b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Monica Feeley (b) (4)	30 Oct 2020 12:32:34
	(b) (4)	
User entered 'Hypertensive Urgency' reason for change: Data Entry Error	Monica Feeley (b) (4)	30 Oct 2020 12:32:34
	(b) (4)	
Query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency" answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 12:32:19
	(b) (4)	
Query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 12:32:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:32:29
	(b) (4), (b) (6)	
User opened query 'Safety Medical Query: The subject was admitted to the hospital for confusion and dizziness secondary to uncontrolled hypertension. It appears, confusion was a symptom of uncontrolled hypertension. If correct, please consider updating event term to "Hypertensive urgency" (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:10:32
User opened query 'PV Query: Please provide the underlying cause of the confusion and consider updating the event term to the final diagnosis. If no etiology was determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:32
User coded data point as SOC: Psychiatric disorders, HLGT: Deliria (incl confusion), HLT: Confusion and disorientation, PT: Confusional state, LLT: Confusion - version MedDRA\23.0.	Coder Import (b) (4)	25 Sep 2020 22:13:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Sep 2020 22:13:54
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 22:12:34
User entered 'Confusion'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:00
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:01
User entered 'No (N)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:04
User entered 'No (N)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:06
User entered '25 Sep 2020'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:07
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 22:12:24

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:09
User entered 'No (N)' reason for change: New Information	Xhoi Mitre (b) (4)	02 Oct 2020 23:26:48
	(b) (4)	
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:11
User entered '30 Sep 2020' reason for change: New Information	Xhoi Mitre (b) (4)	02 Oct 2020 23:26:48
	(b) (4)	
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:14
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 22:12:24

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:17
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:21
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:22
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:24
	(b) (4), (b) (6)	
User closed query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:36:51
Query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' answered with 'updated' (Site from DM).	Xhoi Mitre (b) (4)	02 Oct 2020 23:21:00
	(b) (4)	
User opened query 'Per CDM: Thank you for your response. Please update Hospital Discharge Date when known. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:41:38
	(b) (4), (b) (6)	
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)	29 Sep 2020 18:41:04
	(b) (4), (b) (6)	
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 'was admitted 25SEP2020. not discharged and not admitted to ICU' (Site from System).	Xhoi Mitre (b) (4)	25 Sep 2020 22:13:06
	(b) (4)	
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	25 Sep 2020 22:12:24
User entered 'I'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:26
User entered '25 Sep 2020'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:28
User entered '30 Sep 2020' reason for change: New Information	Xhoi Mitre (b) (4)	02 Oct 2020 23:26:48
	(b) (4)	
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:30
User entered 'No (N)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:31
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:33
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:34
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:36
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:37
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:39
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:41
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:11:55
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 19:07:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	19 Oct 2020 19:06:48
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:49:19
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:20:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 13:57:16
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 17:59:09
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	25 Jan 2021 17:58:59
DataPoint Un-verified.	Austin Kim (b) (4)	25 Jan 2021 17:58:59
User entered '0' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 17:58:59
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	Austin Kim (b) (4)	25 Jan 2021 17:58:20
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	System	25 Jan 2021 17:58:20
DataPoint Verified.	(b) (4), (b) (6)	29 Nov 2020 03:17:56
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 19:56:47
	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:20:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Un-verified.	Austin Kim (b) (4)	25 Jan 2021 17:58:20
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Austin Kim (b) (4)	25 Jan 2021 17:58:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 19:56:49
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:51
User entered '0'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Xhoi Mitre (b) (4)	02 Oct 2020 23:26:48
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:56:54
User entered empty.	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	11 Nov 2020 21:43:36
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:43:32
User closed query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	Monica Feeley (b) (4)	10 Nov 2020 22:22:19
Query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	10 Nov 2020 22:21:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:12:31
User opened query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:12:21
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:23:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:50:09
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:50:04
User closed query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.' (Site from DM).		

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
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). DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:33:33
	Monica Feeley (b) (4)	30 Oct 2020 13:12:54
User entered 'PT RECEIVED SECOND VACCINE 16SEP2020. PATIENT WAS FOUND THIS MORNING WALKING OUTSIDE DISORIENTED BY A BYSTANDER WHO CALLED EMS. ALSO REPORTS DIZZINESS. WAS ADMITTED TODAY BECAUSE OF THE CONFUSION. HAD A CEREBRAL SCAN WITHOUT SIGNIFICANT CHANGES FROM PREVIOUS SCAN DONE IN 2019. HAD HTN IN THE ED (UP TO 204 SYSTOLIC) HE IS KNOWN WITH HTN, WHICH IS CAPTURED IN THE MEDICAL HISTORY. 02 OCT 2020- SAE DISCHARGE UPDATE: PT WAS HOSPITALIZED FROM 9/25 TO 9/30 FOR CONFUSION IN THE CONTEXT OF UNCONTROLLED HYPERTENSION. BP WAS CONTROLLED DURING HOSPITALIZATION WITH LISINOPRIL 5MG QD WHICH MUCH IMPROVEMENT. PT WAS BACK TO BASELINE AT DISCHARGE. 30OCT2020 updated: head CT (25SEP2020), chest XR (25SEP2020), brain MRI (25SEP2020), cervical spine MRI (28SEP2020) - all imaging showed no acute finding that can explain confusion. EEG (29SEP2020) - no epileptiform or lateralizing abnormalities LP (26SEP2020) - WBC count of 1, HSV PCR negative, Viral culture negative, bacteria culture negative' reason for change: New Information	Monica Feeley (b) (4)	30 Oct 2020 13:12:54

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'head CT (25SEP2020), chest XR (25SEP2020), brain MRI (25SEP2020), cervical spine MRI (28SEP2020) - all imaging showed no acute finding that can explain confusion. EEG (29SEP2020) - no epileptiform or lateralizing abnormalities LP (26SEP2020) - WBC count of 1, HSV PCR negative, Viral culture negative, bacteria culture negative updates made to narrative as well as con procedures' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 13:12:34
Query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' answered with 'This AE is reflective of this' (Site from DM).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 12:32:47
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had a worsening of hypertension. However, there is no corresponding AE record that match this information. Please update to record the worsening event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 20:37:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 19:57:05
User closed query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 16:13:53
User closed query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 16:13:42
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 16:13:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:13:16
User closed 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)	20 Oct 2020 16:12:51
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sending redacted summary ' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 19:17:07
Query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.	Monica Feeley (b) (4)	19 Oct 2020 19:16:41
' answered with 'updated' (Site from DM).		
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.' answered with '25SEP2020- NP swab, negative' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 19:02:46
Query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' answered with 'see ConMed form. Taking amlodipine JAN2020 - 25SEP2020. Lisinopril from 27SEP2020- current' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 18:52:53
Query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' answered with 'added to ConMed' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 18:51:46

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'we have updated to medical history. diagnosed JAN 2020' (Site from Safety).	Monica Feeley (b) (4)	19 Oct 2020 18:49:55
User opened query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:46:15
User opened query 'PV Query: Please confirm which statin medication the subject was taking (listed on CM eCRF).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:10:06
Query 'PV Query: In addition to confusion, which is reported as the SAE, there is some mention of dizziness and BP at 204 mmHg systolic in this participant with history of hypertension. Please confirm if all SAE and leading diagnostic have been included in the EDC.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:42:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:42:25
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:53:20
User opened query 'PV Query: It was reported the subject had known history of hypertension. Was the subject on antihypertensive therapy prior to study randomization? If so, please update ConMed eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:52:26

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:18
User opened query 'PV Query: Please confirm if hypertension is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If hypertension is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:09
User opened query 'PV Query: In addition to confusion, which is reported as the SAE, there is some mention of dizziness and BP at 204 mmHg systolic in this participant with history of hypertension. Please confirm if all SAE and leading diagnostic have been included in the EDC.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:50:44
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)	05 Oct 2020 13:48:03
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)	05 Oct 2020 13:47:12

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT RECEIVED SECOND VACCINE 16SEP2020. PATIENT WAS FOUND THIS MORNING WALKING OUTSIDE DISORIENTED BY A BYSTANDER WHO CALLED EMS. ALSO REPORTS DIZZINESS. WAS ADMITTED TODAY BECAUSE OF THE CONFUSION. HAD A CEREBRAL SCAN WITHOUT SIGNIFICANT CHANGES FROM PREVIOUS SCAN DONE IN 2019. HAD HTN IN THE ED (UP TO 204 SYSTOLIC) HE IS KNOWN WITH HTN, WHICH IS CAPTURED IN THE MEDICAL HISTORY. 02 OCT 2020- SAE DISCHARGE UPDATE: Pt was hospitalized from 9/25 to 9/30 for confusion in the context of uncontrolled hypertension. BP was controlled during hospitalization with lisinopril 5mg QD which much improvement. Pt was back to baseline at discharge.' reason for change: New Information	Xhoi Mitre (b) (4)	02 Oct 2020 23:26:48
User entered 'Pt received second vaccine 16SEP2020. Patient was found this morning walking outside disoriented by a bystander who called EMS. Also reports dizziness. Was admitted today because of the confusion. Had a cerebral scan without significant changes from previous scan done in 2019. Had HTN in the ED (up to 204 Systolic) He is known with HTN, which is captured in the medical history.'	Xhoi Mitre (b) (4)	25 Sep 2020 22:12:24

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 22:12:24

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 22:12:24

US3432202

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 22:12:24

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Cervical spinal stenosis, LLT: Cervical spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 21:05:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 21:05:57
Data point term sent to Coder	System	14 Jan 2021 21:04:55
Coding entries removed.	(b) (4), (b) (6)	14 Jan 2021 21:04:33
User entered 'Cervical Stenosis' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:04:33
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 23:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 23:33:44
Data point term sent to Coder	System	02 Oct 2020 23:32:29
User entered 'Dizziness'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '02 Oct 2020'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User entered empty.	System	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Jan 2021 21:06:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:06:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Jan 2021 21:05:54
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Jan 2021 21:05:54
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Jan 2021 21:05:54
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:05:54
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Jan 2021 21:05:27
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User entered empty.	System	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Oct 2020 23:32:08
User entered '1' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Oct 2020 23:32:00
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:05:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User entered '0'	System	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38
User entered 'I'	System	02 Oct 2020 23:32:00

US3432202

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:38

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 18:38:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 18:38:32
Data point term sent to Coder	System	15 Mar 2021 18:38:16
User entered 'Basal Cell Carcinoma'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'No (N)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '20 Feb 2021'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User entered empty.	System	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:08
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:08
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User entered '19 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User entered empty.	System	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	15 Mar 2021 19:43:53
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	15 Mar 2021 19:43:53
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	15 Mar 2021 18:38:06
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Per CDM: The AE started after the first dose however the relationship to IP is not recorded as either Related / Not related. Please update as appropriate else clarify.' (Site from DM). Query 'Per CDM: The AE started after the first dose however the relationship to IP is not recorded as either Related / Not related. Please update as appropriate else clarify.' answered with 'updated to not related' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:19:21
Query 'Per CDM: The AE started after the first dose however the relationship to IP is not recorded as either Related / Not related. Please update as appropriate else clarify.' answered with 'updated to not related' (Site from DM).	Monica Feeley (b) (4)	24 Mar 2021 18:57:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Monica Feeley (b) (4)	24 Mar 2021 18:56:58
User opened query 'Per CDM: The AE started after the first dose however the relationship to IP is not recorded as either Related / Not related. Please update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:10:36
User entered 'Not Applicable (NOT APPLICABLE)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Not Applicable (NOT APPLICABLE)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Not Applicable (NOT APPLICABLE)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '0'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'I'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:08
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:02:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 19:43:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 19:43:53
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 18:38:06
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User entered '0'	System	15 Mar 2021 19:43:53
User entered '1'	System	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42
User entered 'I'	System	15 Mar 2021 18:38:06

US3432202

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:34:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:45:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User closed query 'Per CDM: Diary dose 2 temperature day log #1, #2 indicates medication was taken for Pain / Fever. However there is no medication recorded for the corresponding dates. Please review and update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:17:57
Query 'Per CDM: Diary dose 2 temperature day log #1, #2 indicates medication was taken for Pain / Fever. However there is no medication recorded for the corresponding dates. Please review and update as appropriate else clarify.' answered with 'NSAIDS already open in con meds PRN covering the corresponding dates. Thank you' (Site from DM).	Bruce Bausk (b) (4)	09 Mar 2021 19:52:40
User opened query 'Per CDM: Diary dose 2 temperature day log #1, #2 indicates medication was taken for Pain / Fever. However there is no medication recorded for the corresponding dates. Please review and update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:37:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:32:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 20:58:36

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIBENCLAMIDE, PRODUCTSYNONYM: GLYBURIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:01:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:01:05
Data point term sent to Coder	System	19 Aug 2020 21:00:36
User entered 'glyburide'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'diabetes mellitus'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:31
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:01:45
Un-reviewed for Data Management.	Monica Feeley (b) (4)	21 Aug 2020 22:00:57
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:00:57
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:01:27
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:19:12
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:00:25
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:13
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Un-reviewed for Data Management.	Monica Feeley (b) (4)	21 Aug 2020 22:00:57
	(b) (4)	
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:00:57
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 17:41:30
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:00:32
User entered 'No (N)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 21:00:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:00:13
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:00:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:00:13

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:14
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:04:49
Data point term sent to Coder	System	26 Aug 2020 12:50:45
User entered 'lorazepam'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:07
User entered 'No (N)'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:09
User entered 'Anxiety'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
User entered '0.5' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:31:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:30:11
	(b) (4)	
User entered 'UNK'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
	(b) (4)	
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 21:08:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 12:50:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 12:50:03
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Monica Feeley (b) (4)	26 Aug 2020 12:50:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 12:49:47
User entered empty.	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'I'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	26 Aug 2020 12:49:47
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:49:47

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:02:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:02:06
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 21:01:38
User entered 'Glipizide'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'diabetes mellitus'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:42
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:02:29
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:02:20
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:02:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:21:57
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:01:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:28
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:02:20
	(b) (4)	
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:01:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 21:01:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:01:28
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:01:28
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:01:28

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:03:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:03:06
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 21:02:38
User entered 'Prozac'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Anxiety'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:46
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:03:39
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:03:27
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:03:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:08
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:04:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:02:18
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:03:27
	(b) (4)	
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:24:43
Data point term sent to Coder DataPoint Un-verified.	System Monica Feeley (b) (4)	10 Nov 2020 22:23:25 10 Nov 2020 22:23:01
	(b) (4)	
Coding entries removed.	Monica Feeley (b) (4)	10 Nov 2020 22:23:01
	(b) (4)	
User entered 'SIMVASTATIN' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: HMG COA REDUCTASE INHIBITORS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:02:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:02:45
Data point term sent to Coder	System	07 Sep 2020 21:52:55
User closed query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	07 Sep 2020 21:52:35

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'specific statin not specified ' (Site from System).	Monica Feeley (b) (4)	07 Sep 2020 21:52:35
User opened query 'CDM-Coding: The trade name STATIN can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	01 Sep 2020 06:49:45
User closed query 'Please specify the name of Statin.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 16:27:40
Query 'Please specify the name of Statin.' answered with 'statin name not specified by participant' (Site from CRA).	Monica Feeley (b) (4)	26 Aug 2020 12:51:41
User opened query 'Please specify the name of Statin.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 20:26:13
Data point term sent to Coder	System	19 Aug 2020 21:03:40
User entered 'Statin'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'High cholesterol'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:52
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:04:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:04:09
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:03:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:16
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:04:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:02:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:04:09
	(b) (4)	
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:02:55
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:02:55

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:35:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:35:17
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 21:04:41
User entered 'Pantoprazole'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'duodenal ulcer'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:24:57
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:04:58
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:04:51
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:04:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:27
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:04:49
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:03:51
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:04:51
	(b) (4)	
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown (UNKNOWN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'I'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:03:51
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:03:51

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Please specify name of NSAIDS' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 16:27:59
Query 'Please specify name of NSAIDS' answered with 'NSAID name not specified by participant ' (Site from CRA).	Monica Feeley (b) (4)	26 Aug 2020 12:51:23
User opened query 'Please specify name of NSAIDS' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 20:40:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, PRODUCT: NSAIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:48:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:48:16
Data point term sent to Coder	System	19 Aug 2020 21:04:42
User entered 'NSAIDS'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	04 Nov 2020 16:48:03
(Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	Monica Feeley (b) (4)	19 Oct 2020 18:50:55
' answered with 'see medical history for "daily headaches"' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	01 Oct 2020 09:02:07
(Site from DM).		
User entered 'headache'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unk'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:25:03
Query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Aug 2020 22:05:52
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:05:41
User opened query 'Per CDM: Per query response, please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:04:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:22:35
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Bruce Bausk (b) (4)	19 Aug 2020 21:04:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:04:22
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'unknown' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Aug 2020 22:05:41
	(b) (4)	
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'as needed (PRN)'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 21:04:38
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 21:04:22
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1' reason for change: Data Entry Error	Bruce Bausk (b) (4)	19 Aug 2020 21:04:38
	(b) (4)	
User entered '0'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Bruce Bausk (b) (4)	19 Aug 2020 21:04:22
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:04:22

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'please add to source con-med log' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:43:13
Query 'please add to source con-med log' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	10 Nov 2020 22:24:14
User opened query 'please add to source con-med log' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:39:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 20:49:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 20:49:34
Data point term sent to Coder	System	21 Oct 2020 23:00:22
Coding entries removed.	Megan Powell (b) (4)	21 Oct 2020 23:00:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:54:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:54:31
Data point term sent to Coder	System	27 Aug 2020 13:36:00
Data point term sent to Coder	System	26 Aug 2020 21:59:04

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Ibuprofen'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per DM CLR: This Conmed is given for the AE#1 FOREIGN BODY IN FOOT. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 03:20:18
Query 'Per DM CLR: This Conmed is given for the AE#1 FOREIGN BODY IN FOOT. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Jessica Cauley (b) (4)	04 Jan 2021 18:18:36
User opened query 'Per DM CLR: This Conmed is given for the AE#1 FOREIGN BODY IN FOOT. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:31:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Per DM CLR: Please review and confirm if this indication pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:17:46
User closed query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:48:52

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and confirm if this indication pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' answered with 'Yes, has been updated' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:34
Query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Benign' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:22
User entered 'Foreign Body in Foot' reason for change: Data Entry Error	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:00:16
User opened query 'Per DM CLR: Please review and confirm if this indication pertains to the AE condition of 'FOREIGN BODY IN FOOT'. If yes, please update verbatim for consistency. Please reconcile with AE eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:56
User opened query 'Per DM CLR: Please confirm if this Lesion is benign or malignant; Please update to include the location of the lesion (e.g. left, right or bilateral). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:47
User entered 'foot lesions'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '200'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'as needed (PRN)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 13:35:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 13:35:23
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Monica Feeley (b) (4)	27 Aug 2020 13:35:23
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:58:07
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '21 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1 Sep 2020' reason for change: New Information	Phoebe Cunningham (b) (4)	02 Sep 2020 21:42:11
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Phoebe Cunningham (b) (4)	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User entered empty.	System	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User entered empty.	System	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:01
User entered empty.	System	26 Aug 2020 21:58:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 23:30:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 23:30:56
Data point term sent to Coder	System	02 Oct 2020 23:30:28
User entered 'Amlodipine'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'HTN'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '5'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'UN Jan 2020'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User entered '1'	System	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User entered '1'	System	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:01:56
User entered '804 (804)'	System	02 Oct 2020 23:29:27

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:48
User closed query 'Please revise spelling to Lisinopril' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:43:47
User coded data point as ATC:	Coder Import (b) (4)	10 Nov 2020 22:27:45
CARDIOVASCULAR SYSTEM, ATC: AGENTS	(b) (4)	
ACTING ON THE RENIN-ANGIOTENSIN		
SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:		
ACE INHIBITORS, PLAIN, PRODUCT:		
LISINOPRIL - version		
WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Nov 2020 22:27:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	10 Nov 2020 22:26:27
Query 'Please revise spelling to Lisinopril' answered	System	10 Nov 2020 22:25:34
by data change (Site from CRA).		
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Nov 2020 22:25:34
	(b) (4)	
Coding entries removed.	Monica Feeley (b) (4)	10 Nov 2020 22:25:34
	(b) (4)	
User entered 'LISINOPRIL' reason for change: Data	Monica Feeley (b) (4)	10 Nov 2020 22:25:34
Entry Error	(b) (4)	
User opened query 'Please revise spelling to	(b) (4), (b) (6)	06 Nov 2020 20:00:13
Lisinopril' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC:	Coder Import (b) (4)	03 Oct 2020 06:58:42
CARDIOVASCULAR SYSTEM, ATC: AGENTS	(b) (4)	
ACTING ON THE RENIN-ANGIOTENSIN		
SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:		
ACE INHIBITORS, PLAIN, PRODUCT:		
LISINOPRIL - version		
WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Oct 2020 06:58:42
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	02 Oct 2020 23:30:26
User entered 'Lisonpril'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

2334 of 2725

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'HTN'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '5'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '27 Sep 2020'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	02 Oct 2020 23:30:17
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:30:17

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:30:17

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 23:30:17

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:27:46
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	10 Nov 2020 22:27:27 10 Nov 2020 22:27:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
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 Nov 2020 15:48:22
Data point term sent to Coder User entered 'Labetalol'	System Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:02 06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:44:27
User closed query 'Please change spelling to HYPERTENSION' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:44:26
Query 'Please change spelling to HYPERTENSION' answered by data change (Site from CRA).	System	10 Nov 2020 22:27:08
User entered 'HYPERTENSION' reason for change: Monica Feeley	(b) (4)	10 Nov 2020 22:27:08
Data Entry Error	(b) (4)	
User opened query 'Please change spelling to HYPERTENSION' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:55:43
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 19:55:21
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hpyertension'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '200'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User entered empty.	System	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User entered empty.	System	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:18
User entered empty.	System	06 Nov 2020 15:39:14

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:20:18
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 Nov 2020 16:20:18
Data point term sent to Coder	System	06 Nov 2020 15:40:03
User entered 'Labetalol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '10'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'other (OTHER)' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 15:42:58
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Twice' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 15:42:58
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User entered empty.	System	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User entered empty.	System	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:22
User entered empty.	System	06 Nov 2020 15:39:45

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:48:22
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 Nov 2020 15:48:22
Data point term sent to Coder	System	06 Nov 2020 15:41:05
User entered 'Labetalol'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '20'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User entered empty.	System	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User entered empty.	System	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:29
User entered empty.	System	06 Nov 2020 15:40:12

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:44:52
User closed query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:44:50
Query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' answered with 'it is listed in discharge summary' (Site from CRA).	Monica Feeley (b) (4)	10 Nov 2020 22:31:56
User opened query 'This medication is not listed in the discharge summary, please verify if it was given to subject, edit as required.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:16:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 20:14:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:47:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:47:19
Data point term sent to Coder	System	06 Nov 2020 15:41:07
User entered 'Hydralazine'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per DM CLR: This Conmed is given for the AE#2 HYPERTENSIVE URGENCY. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 13:57:25
Query 'Per DM CLR: This Conmed is given for the AE#2 HYPERTENSIVE URGENCY. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 17:59:36
User opened query 'Per DM CLR: This Conmed is given for the AE#2 HYPERTENSIVE URGENCY. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:28:45
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '10'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User entered empty.	System	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User entered empty.	System	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:33
User entered empty.	System	06 Nov 2020 15:40:46

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 21:57:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 21:57:16
Data point term sent to Coder	System	27 Jan 2021 21:56:28
Coding entries removed.	Monica Feeley (b) (4)	27 Jan 2021 21:55:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:05:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:05:12
Data point term sent to Coder	System	20 Nov 2020 21:04:53
Coding entries removed.	Monica Feeley (b) (4)	20 Nov 2020 21:04:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:42:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:42:34
Data point term sent to Coder	System	06 Nov 2020 15:42:08
User entered 'Tylenol'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 23:13:08
User closed query 'Per CDM re-query: Per previous query, please update the Indication to include details of the corresponding Adverse Event.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:21:59
Query 'Per CDM re-query: Per previous query, please update the Indication to include details of the corresponding Adverse Event.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	27 Jan 2021 21:55:57
DataPoint Un-verified.	Monica Feeley (b) (4)	27 Jan 2021 21:55:50
User entered 'MILD PAIN IN HOSPITAL (SAE: Hypertensive urgency)' reason for change: Data Entry Error	Monica Feeley (b) (4)	27 Jan 2021 21:55:50
User opened query 'Per CDM re-query: Per previous query, please update the Indication to include details of the corresponding Adverse Event.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:00:44
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 13:57:38
Query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'general mild pain as participant was hospitalized' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 18:00:00
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:21:57
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 21:04:37
	(b) (4)	
User entered 'Mild pain in hospital' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 21:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:45:18
	(b) (4), (b) (6)	
User closed query 'Please check if Indication is correct, edit in source con-med log & EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:45:17
Query 'Please check if Indication is correct, edit in source con-med log & EDC.' answered with 'this is correct.' (Site from CRA).	Monica Feeley (b) (4)	10 Nov 2020 22:32:38
	(b) (4)	
User opened query 'Please check if Indication is correct, edit in source con-med log & EDC.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:57:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 19:56:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '1000'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User entered empty.	System	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User entered empty.	System	06 Nov 2020 15:41:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:39
User entered empty.	System	06 Nov 2020 15:41:15

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'condition has not worsened- dose changed to control hypertension more effectively' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:40:04
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	Julia Klopfer (b) (4) (b) (4)	07 Apr 2021 22:31:21
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:24:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:45:49
User closed query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:45:47
Query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' answered with 'this is what notes said' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:36:28
User opened query 'please check if this medication was given to subject as subject was already on Lisinopril 5mg by 30Sep20.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:22:36

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 20:21:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:58:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:58:19
Data point term sent to Coder	System	06 Nov 2020 15:42:08
User entered 'Lisinopril'	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Hypertension'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '2.5'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:59:31
User entered 'once daily (QD)' reason for change:	Monica Feeley (b) (4)	20 Nov 2020 20:59:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'once (ONCE)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
DataPoint Un-verified.	Monica Feeley (b) (4)	24 Mar 2021 18:42:29
Signature has been broken.	Monica Feeley (b) (4)	24 Mar 2021 18:42:29
User entered '27 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	24 Mar 2021 18:42:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '30 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '0'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered '30 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:55
User entered 'No (N)'	Monica Feeley (b) (4)	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User entered '1'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User entered '1'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:45
User entered '804 (804)'	System	20 Nov 2020 20:59:31
User entered empty.	System	06 Nov 2020 15:41:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:03:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:03:18
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	28 Jan 2021 18:51:49 28 Jan 2021 18:50:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:46:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:46:29
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	27 Jan 2021 21:57:30 27 Jan 2021 21:56:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:04:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:42
	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:00:44
User entered 'Ibuprofen'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 23:13:29
User closed query 'Per CDM re-query: Response "general" noted; Please update it along with indication. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:46:01
Query 'Per CDM re-query: Response "general" noted; Please update it along with indication. Thank you' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	28 Jan 2021 18:51:01
User entered 'MILD General PAIN WHILE IN HOSPITAL (SAE HYPERTENSIVE URGENCY)' reason for change: Data Entry Error	Monica Feeley (b) (4)	28 Jan 2021 18:50:52
User closed query 'Per CDM re-query: Please review if the location of the pain can be provided along with the indication per previous query. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:23:39
User opened query 'Per CDM re-query: Response "general" noted; Please update it along with indication. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:23:34
Query 'Per CDM re-query: Please review if the location of the pain can be provided along with the indication per previous query. Thank you' answered with 'no location of pain. just general' (Site from DM).	Monica Feeley (b) (4)	27 Jan 2021 21:56:44
DataPoint Un-verified.	Monica Feeley (b) (4)	27 Jan 2021 21:56:32
User entered 'MILD PAIN WHILE IN HOSPITAL (SAE Hypertensive urgency)' reason for change: Data Entry Error	Monica Feeley (b) (4)	27 Jan 2021 21:56:32
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:49:51
User opened query 'Per CDM re-query: Please review if the location of the pain can be provided along with the indication per previous query. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:49:49

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'general pain since person was hospitalized' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 18:00:24
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of MILD PAIN . Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:31:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mild pain while in hospital'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '400'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'as needed (PRN)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '28 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User entered empty.	System	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User entered empty.	System	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:02:57
User entered empty.	System	20 Nov 2020 21:00:42

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:03:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:03:04
Data point term sent to Coder	System	20 Nov 2020 21:01:45
User entered 'Senokot'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
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)	26 Jan 2021 14:04:09
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 'This is not a medical condition. Participant was in hospital and typically patients are given medication to combat constipation. ' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 18:00:55
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)	04 Dec 2020 22:02:45
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mild constipation'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:04:07
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'This is what was reported' (Site from DM).	Austin Kim (b) (4)	25 Jan 2021 18:01:03
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:02:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '2'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'tablet (TABLET)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '26 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User entered '2'	System	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User entered '1'	System	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:03:01
User entered '804 (804)'	System	20 Nov 2020 21:01:38

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:04:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:04:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:02:49
User entered 'Lovenox'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'blood clot prevention'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '40'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '28 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '0'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30 Sep 2020'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User entered '1'	System	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User entered '1'	System	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:22:17
User entered '804 (804)'	System	20 Nov 2020 21:02:29

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:16:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:16:08
	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 21:15:28
User entered 'Metformin'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'DM'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '1000'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4), (b) (6)	20 Nov 2020 21:47:20
DataPoint Verified.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
User entered 'mg (mg)'	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'I'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:14:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 21:14:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:14:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:14:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:05
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
Data point term sent to Coder	System	20 Nov 2020 21:21:41
Coding entries removed.	Monica Feeley (b) (4)	20 Nov 2020 21:21:17
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 21:19:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 21:19:08
Data point term sent to Coder	System	20 Nov 2020 21:18:37
User entered 'Trazodone'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'ANXIETY and depression' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 21:21:17
	(b) (4)	
User entered 'anxiety'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '100'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'I'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:18:18
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:18:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:18:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:18:18

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:38:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:38:03
Data point term sent to Coder	System	20 Nov 2020 21:21:41
User entered 'Mirtazapine'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:21:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'depression'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '30'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'once daily (QD)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'I'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:21:07
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:21:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:21:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 21:21:07

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:27:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:27:07
Data point term sent to Coder	System	20 Nov 2020 21:26:45
User entered 'Ibuprofen'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 21:26:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'unknown'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '200'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'other (OTHER)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered '8x daily'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'I'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'Yes (Y)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered empty.	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:47:20
User entered 'No (N)'	Monica Feeley (b) (4)	20 Nov 2020 21:26:44
	(b) (4)	

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

US3432202

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:26:44

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:06
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:03:17
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:33:35

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:38
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '20 Aug 2020'	Xhoi Mitre (b) (4)	27 Aug 2020 22:39:33
	(b) (4)	

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'FOREIGN BODY REMOVAL from foot' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	27 Aug 2020 22:39:48
User entered 'Foreign body removal'	Xhoi Mitre (b) (4)	27 Aug 2020 22:39:33

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Xhoi Mitre (b) (4)	27 Aug 2020 22:39:33
	(b) (4)	

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Xhoi Mitre (b) (4)	27 Aug 2020 22:39:33
	(b) (4)	

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '25 Sep 2020'	Monica Feeley (b) (4)	19 Oct 2020 19:15:14

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'CT Head and Neck' reason for change:	Monica Feeley (b) (4)	19 Oct 2020 19:16:10
Data Entry Error	(b) (4)	
User entered 'Confusion'	Monica Feeley (b) (4)	19 Oct 2020 19:15:14
	(b) (4)	

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	19 Oct 2020 19:15:14

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4)	19 Oct 2020 19:15:14

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '25 Sep 2020'	Monica Feeley (b) (4)	19 Oct 2020 19:15:37

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'MRI Brain'	Monica Feeley (b) (4)	19 Oct 2020 19:15:37

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	19 Oct 2020 19:15:37

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4)	19 Oct 2020 19:15:37

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered '28 Sep 2020'	Monica Feeley (b) (4)	19 Oct 2020 19:15:53

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'MRI Neck'	Monica Feeley (b) (4)	19 Oct 2020 19:15:53

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	19 Oct 2020 19:15:53

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:25:32
User entered empty.	Monica Feeley (b) (4)	19 Oct 2020 19:15:53

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:33
User closed query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:46:32
Query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' answered with 'udpated' (Site from CRA).	Monica Feeley (b) (4)	10 Nov 2020 22:42:12
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Nov 2020 22:42:08
User entered '25 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Nov 2020 22:42:08
User opened query 'Per AE narrative and discharge summary CXR was done on 25sep20, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:10:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '29 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 14:41:26

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Chest X-Ray'	Monica Feeley (b) (4)	06 Nov 2020 14:41:26

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	06 Nov 2020 14:41:26

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 14:41:26

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:58
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '25 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 14:49:49

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:58
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'ECG'	Monica Feeley (b) (4)	06 Nov 2020 14:49:49

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:58
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	06 Nov 2020 14:49:49

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:58
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 14:49:49

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered '29 Sep 2020'	Monica Feeley (b) (4)	06 Nov 2020 14:50:02

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'EEG'	Monica Feeley (b) (4)	06 Nov 2020 14:50:02

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	06 Nov 2020 14:50:02

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:52
User entered empty.	Monica Feeley (b) (4)	06 Nov 2020 14:50:02

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:08
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:03:08
User entered '19 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 19:03:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered '12 Mar 2021'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:09

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Moh's Surgery'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:09

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered 'Adverse Event (AE)'	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:09

US3432202

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:24
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 18:34:09

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '28/Sep/2020 08:53'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:02

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)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '05/Oct/2020 09:29'	System	05 Oct 2020 13:29:38

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:02

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)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:18:02
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 13:29:38

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
User entered '20/Oct/2020 16:18'	System	20 Oct 2020 16:18:13

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:02

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)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:18:17
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 16:18:13

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:17
User entered '30/Oct/2020 15:34'	System	30 Oct 2020 19:34:48

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:02

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)	19 Feb 2021 01:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 16:35:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:17
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 19:34:48

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '11/Nov/2020 16:47'	System	11 Nov 2020 21:47:49

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:34:02

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)	14 Apr 2021 15:08:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 16:35:04
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 21:47:49

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:37
User entered 'USA-US078-2020-MRNA-1273-P301000003'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Yes (Y)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'No (N)'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Lindsey'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'Baden'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:53:40
User entered 'MA'	System	28 Sep 2020 12:53:24

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:29:30
User entered 'US'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '6'	System	26 Jan 2021 16:34:58
User entered '5'	System	11 Nov 2020 21:47:49
User entered '4'	System	30 Oct 2020 19:34:48
User entered '3'	System	20 Oct 2020 16:18:13
User entered '2'	System	05 Oct 2020 13:29:38
User entered '1'	System	28 Sep 2020 12:53:51

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:34:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:08:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
User entered '26/Jan/2021 11:34'	System	26 Jan 2021 16:34:58

US3432202

Folder: SAE USA-US078-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:34:02

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)	14 Apr 2021 15:08:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 16:35:04
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 16:34:58