

US3532020 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:44:42

All time stamps listed in this document are displayed in GMT

US3532020

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

[Participant ID](#)

US3532020

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

US3532020

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

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

Visit date (dd MMM yyyy)	13 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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US3532020

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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

US3532020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	OSTEOARTHRITIS-KNEES,BACK AND LEGS
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

US3532020

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	VISUAL MIGRAINES
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)	

US3532020

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3532020

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	CAESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	RHINOPLASTY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	ABNOMINAL FLOATING GAS
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 (11)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	TOE (SKIN) FUNGAL INFECTION
Start date (dd MMM yyyy)	UN DEC 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3532020

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Condition	DERMAL FILLER INJECTIONS
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3532020

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:44 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:44
Height (<i>xxx.x</i>)	167 cm
Weight (<i>xxx.x</i>)	82.1 kg
BMI (<i>xxx.x</i>)	29.43813 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Date of assessment (dd MMM yyyy) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1999

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 10:51:42

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 186161

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Height	ND - Not Done
Weight	ND - Not Done

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

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)	13 AUG 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:44
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

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)	13 AUG 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:22
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:48 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:48

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) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

13 AUG 2020 12:25

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	13 AUG 2020 12:15
Nasopharyngeal Swab 2	No		

US3532020

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:26

PC Open Date & Time

13 AUG 2020 13:08

PC Close Date & Time

13 AUG 2020 15:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	14 AUG 2020 10:15
PC Open Date & Time	13 AUG 2020 16:33
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

14 AUG 2020 20:43

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 17:56

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

98.2 °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

16 AUG 2020 18:13

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 18:38

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

18 AUG 2020 19:52

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

19 AUG 2020 19:02

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

13 AUG 2020 13:26

PC Open Date & Time

13 AUG 2020 13:08

PC Close Date & Time

13 AUG 2020 15:38

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 10:18

PC Open Date & Time

13 AUG 2020 16:33

PC Close Date & Time

14 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

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

1

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

14 AUG 2020 20:45

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

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

1

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

15 AUG 2020 17:57

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

16 AUG 2020 18:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

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

17 AUG 2020 18:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

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

18 AUG 2020 19:51

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

19 AUG 2020 19:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:27
PC Open Date & Time	13 AUG 2020 13:08
PC Close Date & Time	13 AUG 2020 15:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 10:19
PC Open Date & Time	13 AUG 2020 16:33
PC Close Date & Time	14 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:48
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

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)

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:13
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

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 ☒

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EAB) (1725)

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:40
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:52
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:01
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 21 AUG 2020 00:26

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 22 AUG 2020 00:04

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp 23 AUG 2020 08:22

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 11

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 ☐

PC Time Stamp 24 AUG 2020 00:58

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 12

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 ☐

PC Time Stamp 24 AUG 2020 22:23

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 13

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 ☐

PC Time Stamp 26 AUG 2020 00:34

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 14

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 ☐

PC Time Stamp 26 AUG 2020 21:10

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 15

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 ☐

PC Time Stamp	27 AUG 2020 21:00
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PC Open Date & Time	27 AUG 2020 12:00
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PC Close Date & Time	28 AUG 2020 11:59
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US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 16

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 ☐

PC Time Stamp 28 AUG 2020 23:11

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 17

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 ☐

PC Time Stamp 30 AUG 2020 01:19

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 18

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 ☐

PC Time Stamp 30 AUG 2020 19:24

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 19

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 ☐

PC Time Stamp 31 AUG 2020 23:54

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 20

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 ☐

PC Time Stamp 01 SEP 2020 23:07

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 21

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 ☐

PC Time Stamp 02 SEP 2020 17:05

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 22

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 ☐

PC Time Stamp 03 SEP 2020 20:53

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 23

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 ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 24

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 ☐

PC Time Stamp 05 SEP 2020 16:50

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 25

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 ☐

PC Time Stamp 06 SEP 2020 20:15

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 26

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 ☐

PC Time Stamp 08 SEP 2020 02:05

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 27

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 ☐

PC Time Stamp 09 SEP 2020 00:49

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 28

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 ☐

PC Time Stamp 09 SEP 2020 14:20

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 29

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 ☐

PC Time Stamp 10 SEP 2020 13:38

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 30

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 ☐

PC Time Stamp 11 SEP 2020 15:42

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 31

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 ☐

PC Time Stamp 12 SEP 2020 22:48

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 32

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 ☐

PC Time Stamp 13 SEP 2020 18:41

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 33

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 ☐

PC Time Stamp 14 SEP 2020 14:02

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 34

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 ☐

PC Time Stamp 15 SEP 2020 12:44

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 35

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 ☐

PC Time Stamp 16 SEP 2020 13:46

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 36

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 ☐

PC Time Stamp

17 SEP 2020 17:42

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 37

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 ☐

PC Time Stamp 18 SEP 2020 23:07

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 38

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 ☐

PC Time Stamp 19 SEP 2020 16:47

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 39

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 ☐

PC Time Stamp 21 SEP 2020 00:33

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 40

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 ☐

PC Time Stamp 22 SEP 2020 08:36

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 41

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 ☐

PC Time Stamp 23 SEP 2020 11:34

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 42

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 ☐

PC Time Stamp 23 SEP 2020 21:59

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 43

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 ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 44

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 ☐

PC Time Stamp 25 SEP 2020 14:32

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 45

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 ☐

PC Time Stamp 26 SEP 2020 12:48

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 46

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 ☐

PC Time Stamp 27 SEP 2020 16:29

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 47

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 ☐

PC Time Stamp 28 SEP 2020 17:20

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 48

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 ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 49

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 ☐

PC Time Stamp 30 SEP 2020 19:23

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 50

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 ☐

PC Time Stamp 01 OCT 2020 18:03

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 51

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 ☐

PC Time Stamp 03 OCT 2020 11:53

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 52

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 ☐

PC Time Stamp 03 OCT 2020 19:17

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 53

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 ☐

PC Time Stamp 04 OCT 2020 15:19

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 54

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 ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 55

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 ☐

PC Time Stamp	06 OCT 2020 23:09
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PC Open Date & Time	06 OCT 2020 12:00
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PC Close Date & Time	07 OCT 2020 11:59
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US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 56

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 ☐

PC Time Stamp

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 57

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 ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

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	21 AUG 2020 00:28
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

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	22 AUG 2020 00:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 10

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

No ☒

Yes ☐

PC Time stamp

23 AUG 2020 08:22

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

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	24 AUG 2020 00:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

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	24 AUG 2020 22:23
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

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	26 AUG 2020 00:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

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	26 AUG 2020 21:10
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

27 AUG 2020 21:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 16

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

No ☒

Yes ☐

PC Time stamp

28 AUG 2020 23:11

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 17

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

No ☒

Yes ☐

PC Time stamp

30 AUG 2020 01:19

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 18
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 19:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 19

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

No ☒

Yes ☐

PC Time stamp

31 AUG 2020 23:54

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 20
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 23:08
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 21
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	02 SEP 2020 17:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 22
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	03 SEP 2020 20:53
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 24
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	05 SEP 2020 16:50
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 25
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	06 SEP 2020 20:15
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 26
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	08 SEP 2020 02:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 27

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

No ☒

Yes ☐

PC Time stamp

09 SEP 2020 00:49

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 28

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

No ☐

Yes ☒

PC Time stamp

09 SEP 2020 14:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 29
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	10 SEP 2020 13:38
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 30
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	11 SEP 2020 15:42
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 31
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	12 SEP 2020 22:48
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 32
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	13 SEP 2020 18:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 33
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	14 SEP 2020 14:02
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 34

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

No ☐

Yes ☒

PC Time stamp

15 SEP 2020 12:45

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	16 SEP 2020 13:46
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 36
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	17 SEP 2020 17:43
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 37
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	18 SEP 2020 23:07
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 38
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	19 SEP 2020 16:48
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 39
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	21 SEP 2020 00:33
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 40
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	22 SEP 2020 08:36
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 41
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	23 SEP 2020 11:34
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 42
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	23 SEP 2020 22:00
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 43

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 44
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	25 SEP 2020 14:32
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 45
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 SEP 2020 12:48
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 46
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 SEP 2020 16:29
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 47
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 SEP 2020 17:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 48
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 49
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 SEP 2020 19:23
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 50
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 OCT 2020 18:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 51
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	03 OCT 2020 11:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 52
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	03 OCT 2020 19:17
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 53

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

No ☒

Yes ☐

PC Time stamp

04 OCT 2020 15:19

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 54
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 55
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	06 OCT 2020 23:09
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 56
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

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)	18 SEP 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:57
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

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

THIS DOSE WAS HELD AND
DOSAGE WITHDRAWN DUE TO
ADVERSE #2. THE SUBJECT
WILL REMAIN IN STUDY BUT
NO 2ND DOSAGE.

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

18 SEP 2020 15:00

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

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

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:51:42

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:02:24

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:02:25

Generated On: 11 Aug 2021 22:44:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:02:25

Generated On: 11 Aug 2021 22:44:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:38 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:38
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:02:25

Generated On: 11 Aug 2021 22:44:42

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.

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:02:25

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	12:47 (24 HR)
Collection date and time (derived)	19 OCT 2020 12:47

US3532020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:02:25

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 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	13 OCT 2020 00:01:59
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

20 OCT 2020 19:47:08

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 01:13:15

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 01:03:18

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

25 NOV 2020 17:34:53

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 17:26:19
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

05 DEC 2020 15:52:52

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 16:36:57
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

19 DEC 2020 09:34:52

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

26 DEC 2020 11:00:19

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 08:29:43

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

09 JAN 2021 09:38:36

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

16 JAN 2021 09:44:26

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 03:48:59

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

30 JAN 2021 11:51:27

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 14:16:38

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 13:54:45

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 21:47:45

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

28 FEB 2021 03:04:09

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

06 MAR 2021 17:38:33

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

20 MAR 2021 14:27:05

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 243

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 <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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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°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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 <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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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°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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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°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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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23 FEB 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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13 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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°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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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="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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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 ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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"/>

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:44:42

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
Yes	No	28 FEB 2021 03:05:19

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:32:37

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:32:37

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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	VISIT4
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US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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)	11:58 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 11:58
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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.

US3532020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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)	11:58 (24 HR)
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Collection date and time (derived)	29 MAR 2021 11:58
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US3532020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 08:35:14

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 08:35:14

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532020

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:42

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>

US3532020

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:44:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532020

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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

Visit date (dd MMM yyyy)	2 FEB 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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US3532020

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Date of updated informed consent (<i>dd MMM yyyy</i>)	2 FEB 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>)	2 FEB 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

US3532020

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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

US3532020

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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)	2 FEB 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:45
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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)	2 FEB 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:10
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3532020

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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) 2 FEB 2021

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 12:35

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

US3532020

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00-23:59)	12:13 (24 HR)
Collection date and time (derived)	2 FEB 2021 12:13

US3532020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	12:08
Collection Date and Time (derived)	2 FEB 2021 12:08

US3532020

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

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)	1 MAR 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 12:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

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)	1 MAR 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 13:30
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3532020

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

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.

US3532020

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

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) 12:57 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 12:57

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

US3532020

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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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US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 11:50
Temperature (<i>xxx.x</i>)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532020

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:46:19

Generated On: 11 Aug 2021 22:44:42

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.

US3532020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

11:58 (24 HR)

Collection date and time (derived)

29 MAR 2021 11:58

US3532020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:05:51

Generated On: 11 Aug 2021 22:44:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

AEID

Adverse event

SORENESS AT INJECTION SITE

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)

13 AUG 2020

Start time (00:00-23:59)

16:33 (24 HR)

AE start date and time (derived)

13 AUG 2020 16:33

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 AUG 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)

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

AEID

Adverse event

ULNAR NERVE IRRITATION

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)

16 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)

15 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)

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

AEID

Adverse event

EXACERBATION OF
OSTEOARTHRITIS

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)

25 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

SUBJECT HAD EXACERBATION
OF OSTEOARTHRITIS IN
BACK/NECK AREA. WENT TO
ORTHOPEDIST WHO WILL DO
AN MRI ON WEDNESDAY AND
MOST LIKELY GIVE A STEROID
INJECTION. SUBJECT WILL
MAKE US AWARE OF WHEN
THIS HAPPENS

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)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

AEID

Adverse event

WORSENING TOE FUNGAL
INFECTION

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)

24 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 18:46:17

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

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

Yes ☒

No ☐

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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2003	
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"/>

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication LUMIGAN 0.01 %

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA BOTH EYES

Dose per administration 1

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

If dose unit is Other, specify DROP

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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US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify OCCASIONALLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	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) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	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"/>

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication VOLTAREN CREAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	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 (10)

Data signed: (b) (4) 09 Apr 2021 08:23:03

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Name of Medication SIMETHICONE

Prophylaxis Yes ☐
No ☒

Indication GAS

Dose per administration 125

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 4X WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (11)

Data signed: (b) (4) 09 Apr 2021 08:23:03

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Name of Medication TUMS

Prophylaxis Yes ☐
No ☒

Indication GAS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

4X WEEK

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)

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Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (12)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication ULNAR NERVE IRRITATION

Dose per administration UNKNOWN

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 (12)

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Generated On: 11 Aug 2021 22:44:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication ULNAR NERVE IRRITATION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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	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)		16 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)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication KNEE INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication GABBAPENTIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication SPINAL STEROID INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1988	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 08:23:03

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Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify YEARLY

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

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 08:23:03

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Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 220

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) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

	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)	13 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)	16 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication EPIDURAL STEROID
INJECTION-ASCENT (AMNIOTIC
STEM CELLS)

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF
OSTEOARTHRITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		JOINT
Start date (dd MMM yyyy)		11 MAR 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication EPIDURAL STEROID INJECTION

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF
OSTEOARTHRITIS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (20)

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	JOINT	
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

Name of Medication TERBINAFINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING TOE FUNGAL
INFECTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 08:23:03

Generated On: 11 Aug 2021 22:44:42

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

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 SEP 2020	MRI	Adverse Event	

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 18:46:18

Generated On: 11 Aug 2021 22:44:42

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

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 AE #2

US3532020

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:44:42

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 ☐

Audit

US3532020 (Prod: Children's Healthcare of Atlanta)

US3532020

Form: Participant Creation

Generated On: 11 Aug 2021 22:44:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'US3532020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:55:03

US3532020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:55:04

US3532020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'SCRN'	System	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:55:05

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	13 Aug 2020 16:05:46
User entered '67' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:05:46
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	13 Aug 2020 16:03:40
User entered '77'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'YEARS'	System	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '67'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Female (F)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'I'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Aug 2020'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2020'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Amendment 2 (2)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:55:04

US3532020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'I'	System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:44:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Per CDM: As there is no medical history condition recorded in log line 12, please consider inactivating the row. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 06:41:59
Query 'Per CDM: As there is no medical history condition recorded in log line 12, please consider inactivating the row. Thank you.' answered with 'Done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	08 Feb 2021 21:33:47
User opened query 'Per CDM: As there is no medical history condition recorded in log line 12, please consider inactivating the row. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:00:36
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:08:48

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:33:27
Data point term sent to Coder	System	13 Aug 2020 18:32:47
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:32:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:32:15
User entered 'Hypothyroidism' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:15
Data point term sent to Coder	System	13 Aug 2020 18:26:29
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:25:33
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:25:33
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:15:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:15:35
Data point term sent to Coder	System	13 Aug 2020 18:15:00
User entered 'Hypertension'	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:32:15
User entered 'un UNK 2003' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:15
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:25:33
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:25:33
User entered 'un UNK 2004'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:32:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	13 Aug 2020 18:25:33
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:25:33
	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 2003'	System	13 Aug 2020 18:32:15
User entered empty.	System	13 Aug 2020 18:25:33
User entered 'Jan 2004'	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2003'	System	13 Aug 2020 18:32:15
User entered empty.	System	13 Aug 2020 18:25:33
User entered '2004'	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 14:05:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 14:05:34
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	21 Oct 2020 05:56:07
' (Site from DM).		
Data point term sent to Coder	System	19 Oct 2020 19:29:44
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:06
' answered with 'done' (Site from DM).	(b) (4)	
Coding entries removed.	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:01
User entered 'GLAUCOMA-bilateral' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:01
' (Site from DM).	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	(b) (4), (b) (6)	29 Sep 2020 11:15:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:21
Data point term sent to Coder	(b) (4)	
	System	13 Aug 2020 18:33:48

PRODUCTION RELEASE (v12.003
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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:32:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:32:55
User entered 'Glaucoma' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:55
Data point term sent to Coder	System	13 Aug 2020 18:26:27
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:26:05
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:26:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:23
Data point term sent to Coder	System	13 Aug 2020 18:16:01
User entered 'Asthma'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:32:55
User entered 'un UNK 2018' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:55
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:26:05
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:26:05
User entered 'un UNK 2004'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:32:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:32:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	13 Aug 2020 18:26:05
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:26:05
	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 2018'	System	13 Aug 2020 18:32:55
User entered empty.	System	13 Aug 2020 18:26:05
User entered 'Jan 2004'	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2018'	System	13 Aug 2020 18:32:55
User entered empty.	System	13 Aug 2020 18:26:05
User entered '2004'	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:58:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:58:54
User closed query 'Per DM CLR: Please review and record the specific anatomical location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	21 Oct 2020 05:56:52
' (Site from DM).		
Query 'Per DM CLR: Please review and record the specific anatomical location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Cindy Lubbers (b) (4)	19 Oct 2020 19:30:01
' answered with 'done' (Site from DM).		
Data point term sent to Coder	System	19 Oct 2020 19:29:44
Coding entries removed.	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:43
User entered 'OSTEOARTHRITIS-knees,back and legs' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:43
User opened query 'Per DM CLR: Please review and record the specific anatomical location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 11:16:01
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:20

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	13 Aug 2020 18:33:48
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:33:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:33:25
User entered 'osteoarthritis' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:25
Data point term sent to Coder	System	13 Aug 2020 18:28:33
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:27:43
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:43
Data point term sent to Coder	System	13 Aug 2020 18:27:30
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:23
Data point term sent to Coder	System	13 Aug 2020 18:16:02
User entered 'Seasonal Allergies'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	13 Aug 2020 18:33:25
User entered 'un UNK 1988' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:25
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:27:43
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:43
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered 'un UNK 2000'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered '0'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:33:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:25
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:27:43
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:43
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered '0'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:15:30

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1988'	System	13 Aug 2020 18:33:25
User entered empty.	System	13 Aug 2020 18:27:43
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered 'Jan 2000'	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1988'	System	13 Aug 2020 18:33:25
User entered empty.	System	13 Aug 2020 18:27:43
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
User entered '2000'	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:51
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
	(b) (4)	
	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:51
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:51
	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine with aura, LLT: Ophthalmic migraine - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:21
Data point term sent to Coder	System	13 Aug 2020 18:33:48
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:33:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:33:44
User entered 'visual migraines' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:44
Data point term sent to Coder	System	13 Aug 2020 18:28:34
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:27:56
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:56
Data point term sent to Coder	System	13 Aug 2020 18:27:30
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:24
Data point term sent to Coder	System	13 Aug 2020 18:16:03
User entered 'wrist fracture'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	13 Aug 2020 18:33:44
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:27:56
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:56
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User entered '01 Aug 2020'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:33:44
DataPoint activated with code reason code Data required.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User entered '0'	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:33:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:44
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:27:56
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:27:56
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
User entered '0'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:27:56
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:58
User entered 'Aug 2020'	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:27:56
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:58
User entered '2020'	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:58
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
	(b) (4)	
	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:58
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:58
	(b) (4)	
	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:22
Data point term sent to Coder	System	13 Aug 2020 18:34:49
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:34:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:34:05
User entered 'seasonal allergies' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:34:05
Data point term sent to Coder	System	13 Aug 2020 18:28:34
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:28:11
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:17:24
Data point term sent to Coder	System	13 Aug 2020 18:17:04
User entered 'osteoarthritis'	Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:34:05
User entered 'un UNK 1995' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:34:05
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:28:11
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:11
User entered 'un UNK 2018'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:34:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:34:05
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:28:11
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:17:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:17:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:17:57
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:16:46
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1995'	System	13 Aug 2020 18:34:05
User entered empty.	System	13 Aug 2020 18:28:11
User entered 'Jan 2018'	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1995'	System	13 Aug 2020 18:34:05
User entered empty.	System	13 Aug 2020 18:28:11
User entered '2018'	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Caesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:48:21
Data point term sent to Coder	System	22 Aug 2020 16:46:52
Coding entries removed.	Cindy Lubbers (b) (4)	22 Aug 2020 16:45:54
User entered 'Caesarean section' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:45:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:35:22
Data point term sent to Coder	System	13 Aug 2020 18:34:51
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:34:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:34:28
User entered 'c-section' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:34:28
Data point term sent to Coder	System	13 Aug 2020 18:28:35
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:28:26
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:19:29

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Aug 2020 18:19:29
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 18:18:05
User entered 'gastroesophageal reflux'	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:34:28
User entered 'un UNK 1981' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:34:28
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:28:26
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:26
User entered 'un UNK 1985'	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Aug 2020 16:45:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 16:45:54
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:45:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 18:28:26
User entered empty; reason for change Data Entry Error	System	13 Aug 2020 18:28:26
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:28:26
	(b) (4)	13 Aug 2020 18:17:51
	Laila Hussaini (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'un UNK 1981' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:45:54
User entered empty.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1981'	System	13 Aug 2020 18:34:28
User entered empty.	System	13 Aug 2020 18:28:26
User entered 'Jan 1985'	System	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1981'	System	13 Aug 2020 18:34:28
User entered empty.	System	13 Aug 2020 18:28:26
User entered '1985'	System	13 Aug 2020 18:17:51

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1981'	System	22 Aug 2020 16:45:54
User entered empty.	System	13 Aug 2020 18:17:51

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1981'	System	22 Aug 2020 16:45:54
User entered empty.	System	13 Aug 2020 18:17:51

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 12:08:42
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:16:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Rhinoplasty, LLT: Rhinoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:48:21
Data point term sent to Coder	System	22 Aug 2020 16:46:52
User entered 'Rhinoplasty' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	22 Aug 2020 16:46:41
Data point term sent to Coder	System	13 Aug 2020 18:35:52
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:35:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:35:16
User entered 'rhinoplogy' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:35:16
Data point term sent to Coder	System	13 Aug 2020 18:29:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:28:38
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:28:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:20:34

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Aug 2020 18:20:34
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 18:19:07
User entered 'Diverticulitis'	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:35:16
User entered 'un UNK 1996' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:35:16
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	13 Aug 2020 18:28:38
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:28:38
User entered 'un UNK 2013'	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Aug 2020 16:46:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 16:46:41
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:46:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 18:28:38
User entered empty; reason for change Data Entry Error	System	13 Aug 2020 18:28:38
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:28:38
	(b) (4)	13 Aug 2020 18:18:40
	Laila Hussaini (b) (4)	
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'un UNK 1996' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:46:41
User entered empty.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1996'	System	13 Aug 2020 18:35:16
User entered empty.	System	13 Aug 2020 18:28:38
User entered 'Jan 2013'	System	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1996'	System	13 Aug 2020 18:35:16
User entered empty.	System	13 Aug 2020 18:28:38
User entered '2013'	System	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1996'	System	22 Aug 2020 16:46:41
User entered empty.	System	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1996'	System	22 Aug 2020 16:46:41
User entered empty.	System	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:00:05
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Abdominal distension, LLT: Abdominal bloating - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 08:37:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 08:37:38
Data point term sent to Coder	System	19 Oct 2020 19:32:55
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. Otherwise, clarify. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:32:12
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:32:07
User entered 'Abnominal floating GAS' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:32:07
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:15:10
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Flatulence, LLT: Gas - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:37:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:37:26
Data point term sent to Coder	System	13 Aug 2020 18:37:00
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:36:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:36:03

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
User entered 'Gas' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:36:03
Data point term sent to Coder	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:29:39
	System	13 Aug 2020 18:29:36
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:29:36
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:22:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:22:31
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 18:21:13
User entered 'prostate cancer'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	13 Aug 2020 18:36:10
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:29:36
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:29:36
User entered 'un Aug 2011'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:36:10
User entered '0'	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:36:03
User entered 'Yes (Y)' reason for change: Data Entry Error	System	13 Aug 2020 18:36:03
User opened query 'Data is required. Please complete.' (Site from System).	Laila Hussaini (b) (4)	13 Aug 2020 18:36:03
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	System	13 Aug 2020 18:29:36
	Laila Hussaini (b) (4)	13 Aug 2020 18:29:36
	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:29:36
User entered 'un Oct 2011'	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:29:36
User entered 'Aug 2011'	System	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:29:36
User entered '2011'	System	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:29:36
User entered 'Oct 2011'	System	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:29:36
User entered '2011'	System	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:50:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:50:53
Data point term sent to Coder	System	08 Sep 2020 22:50:10
Query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' answered with 'corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	08 Sep 2020 22:49:28
User entered 'Menopause' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	08 Sep 2020 22:49:21
User opened query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 15:54:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 09:47:46
Query 'Data is required. Please complete.' answered with 'LINE ENTERED IN ERROR' (Site from System).	Laila Hussaini (b) (4) (b) (4)	26 Aug 2020 02:07:55
Data point term sent to Coder	System	13 Aug 2020 18:30:40
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:30:17
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:29:55
Data point term sent to Coder	System	13 Aug 2020 18:27:30
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:26:37
Data point term sent to Coder	System	13 Aug 2020 18:21:15
User entered 'robotic prostatectomy'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:20:56

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'un UNK 1999' reason for change: Data Entry Error	(b) (4) Cindy Lubbers (b) (4)	08 Sep 2020 22:49:21
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	26 Aug 2020 02:07:44
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:30:17
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered 'un Oct 2011'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	08 Sep 2020 22:49:36
User entered '0' reason for change: Data Entry Error	System	08 Sep 2020 22:49:36
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	Cindy Lubbers (b) (4)	08 Sep 2020 22:49:36
User closed query 'Per CDM: As data entered in error keep data field blank.' (Site from DM).	(b) (4)	08 Sep 2020 22:49:21
Query 'Per CDM: As data entered in error keep data field blank.' answered with 'Entered line in error' (Site from DM).	System	31 Aug 2020 15:53:03
User opened query 'Per CDM: As data entered in error keep data field blank.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 20:18:50
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Aug 2020 09:54:50
DataPoint activated with code reason code Data required.	(b) (4)	26 Aug 2020 02:07:44
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
User entered '0'	(b) (4)	13 Aug 2020 18:26:37
	Laila Hussaini (b) (4)	13 Aug 2020 18:20:56
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	08 Sep 2020 22:49:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 09:47:57
Query 'Data is required. Please complete.' answered with 'LINE ENTERED IN ERROR' (Site from System).	Laila Hussaini (b) (4)	26 Aug 2020 02:07:58
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:30:17
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:56

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered 'un Oct 2011'	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:20:56
	(b) (4)	

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
DataPoint activated with code reason code Data required.	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered '0'	(b) (4) Laila Hussaini (b) (4)	13 Aug 2020 18:20:56

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 1999'	System	08 Sep 2020 22:49:21
User entered empty.	System	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered 'Oct 2011'	System	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '1999'	System	08 Sep 2020 22:49:21
User entered empty.	System	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	13 Aug 2020 18:26:37
User entered '2011'	System	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:37
User entered 'Oct 2011'	System	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	13 Aug 2020 18:30:17
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	13 Aug 2020 18:29:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Aug 2020 18:26:37
User entered '2011'	System	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal skin infection - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 21:28:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 21:28:17
Data point term sent to Coder	System	06 Apr 2021 20:10:50
User closed query 'DM-Coding: for term TOE FUNGAL INFECTION, Please clarify if that was Fungal skin toe infection or Fungal infection of nail etc.. Please update the term in accordance with your answer	System	06 Apr 2021 20:10:37
' (Site from System).		
Query 'DM-Coding: for term TOE FUNGAL INFECTION, Please clarify if that was Fungal skin toe infection or Fungal infection of nail etc.. Please update the term in accordance with your answer	Cindy Lubbers (b) (4)	06 Apr 2021 20:10:37
' answered with 'corrected' (Site from System).		
User entered 'TOE (skin) FUNGAL INFECTION' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	06 Apr 2021 20:10:30
User opened query 'DM-Coding: for term TOE FUNGAL INFECTION, Please clarify if that was Fungal skin toe infection or Fungal infection of nail etc.. Please update the term in accordance with your answer	Coder Import (b) (4)	30 Mar 2021 14:44:59
' (Site from System).		
Data point term sent to Coder	System	30 Mar 2021 14:28:36
User entered 'Toe Fungal Infection'	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered 'un Dec 2009'	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered '0'	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered 'Yes (Y)'	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered empty.	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered '0'	Etza Peters (b) (4)	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Dec 2009'	System	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2009'	System	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered empty.	System	30 Mar 2021 14:27:59

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 13:42:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 13:42:40
Data point term sent to Coder	System	07 Apr 2021 13:41:58
User entered 'Dermal filler injections'	Cindy Lubbers (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered 'un UNK 2011'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered '0'	Cindy Lubbers (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered 'un UNK 2011'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User entered '0'	Cindy Lubbers (b) (4)	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 2011'	System	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2011'	System	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'Jan 2011'	System	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '2011'	System	07 Apr 2021 13:41:11

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '11:44'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered '13 Aug 2020 11:44'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '167' cm	(b) (4) Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16
DataPoint set to visible.	(b) (4) System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '82.1' kg	(b) (4) Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16
DataPoint set to visible.	(b) (4) System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
Amendment Manager: User entered '29.43813'	System	16 Sep 2020 23:55:10
User entered '29.4'	System	13 Aug 2020 16:12:16
DataPoint set to visible.	System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'kg/m2'	System	13 Aug 2020 16:12:16
DataPoint set to visible.	System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 09:55:12
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'DONE' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	26 Aug 2020 02:08:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4) (b) (4)	26 Aug 2020 02:08:37
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 11:12:12
User entered '97.4' F	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered 'Oral (Oral)'	(b) (4)	
	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16
	(b) (4)	

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 02:08:37
User entered '66'	Laila Hussaini (b) (4)	13 Aug 2020 16:12:16
	Cindy Lubbers (b) (4)	
	(b) (4)	

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'bpm'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 02:08:37
User entered '18'	Laila Hussaini (b) (4)	13 Aug 2020 16:12:16
	Cindy Lubbers (b) (4)	
	(b) (4)	

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'breaths/min'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 02:08:37
User entered '129'	Laila Hussaini (b) (4)	13 Aug 2020 16:12:16
	Cindy Lubbers (b) (4)	
	(b) (4)	

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'mmHg'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 02:08:37
User entered '84'	Laila Hussaini (b) (4)	13 Aug 2020 16:12:16
	Cindy Lubbers (b) (4)	
	(b) (4)	

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User entered 'mmHg'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28

US3532020

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:36

US3532020

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:36

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:16:36
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'Corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	08 Sep 2020 22:51:07
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:41:09
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	13 Aug 2020 16:41:42
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:41:42
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	13 Aug 2020 16:40:49
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'un UNK 1999' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	13 Aug 2020 16:41:42
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49
	(b) (4)	

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 16:43:00
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 16:42:44
	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44
	(b) (4)	

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

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)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'I'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '0'	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:28
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'VISIT1'	System	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:08:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:08:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:19:21
User entered '186161' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:42

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 14:44:23
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:59:42

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Aug 2020 16:58:39
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'nd' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:20:52
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 12:36:38
User entered '167' cm	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Aug 2020 16:58:39
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'nd' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:20:52
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 12:36:38
User entered '167' cm	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '11:44'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '13 Aug 2020 11:44'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '97.4' F	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '66'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'bpm'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '18'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'breaths/min'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '129'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'mmHg'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '84'	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'mmHg'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Aug 2020 16:58:39
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'nd' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:20:52
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 12:36:38
User entered '167' cm	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:37:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 16:46:32
	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:37:29
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
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) (4), (b) (6)	17 Aug 2020 16:38:23
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).		13 Aug 2020 18:37:29
User entered '13:22' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '13 Aug 2020 13:22'	System	13 Aug 2020 18:37:29
User entered empty.	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '97.6' F reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	13 Aug 2020 18:37:29
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:37:48
User entered '78' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'bpm'	System	13 Aug 2020 18:37:48
User entered empty.	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:37:48
User entered '18' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'breaths/min'	System	13 Aug 2020 18:37:48
User entered empty.	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:37:48
User entered '124' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'mmHg'	System	13 Aug 2020 18:37:48
User entered empty.	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:37:48
User entered '79' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:37:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 18:37:29
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'mmHg'	System	13 Aug 2020 18:37:48
User entered empty.	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:47

US3532020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:43:47

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '12:48'	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '13 Aug 2020 12:48'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Left Arm (LEFT ARM)'	Cindy Lubbers (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'ONCE'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '12:25'	Cindy Lubbers (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '13 Aug 2020 12:25'	System	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '12:15'	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '13 Aug 2020 12:15'	System	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 17:03:49
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 17:03:43
	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:43
	(b) (4)	

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered empty.	System	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	13 Aug 2020 17:03:54

US3532020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered '1'	System	13 Aug 2020 17:03:54

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:10:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0bcfdf4-026d-4dd3-ac38-ceadbde39e7d' User entered 'Yes (Y)'	System	13 Aug 2020 17:26:04
	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:25:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0bcfdf4-026d-4dd3-ac38-ceadbde39e7d' User entered '97.6'	System	13 Aug 2020 17:26:04
	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:25:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0bcfdf4-026d-4dd3-ac38-ceadbde39e7d' User entered 'No (N)'	System	13 Aug 2020 17:26:04
	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0bcfdf4-026d-4dd3-ac38-ceadbde39e7d' User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:26:04
	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 13:08'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 15:38'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:13:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bd66c73a-bc3e-46b2-b371-0b1f6c6d70c8' User entered 'Yes (Y)'	System	14 Aug 2020 14:15:05
	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:14:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bd66c73a-bc3e-46b2-b371-0b1f6c6d70c8' User entered '97.1'	System	14 Aug 2020 14:15:05
	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:14:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bd66c73a-bc3e-46b2-b371-0b1f6c6d70c8'	System	14 Aug 2020 14:15:05
User entered 'No (N)'	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:15:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bd66c73a-bc3e-46b2-b371-0b1f6c6d70c8' User entered '14 Aug 2020 10:15'	System	14 Aug 2020 14:15:05
	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 16:33'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 2'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96e4a2b6-63fe-42cb-9254-ce6b6dbe511e' User entered 'Yes (Y)'	System	15 Aug 2020 00:43:53
	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96e4a2b6-63fe-42cb-9254-ce6b6dbe511e' User entered '97.2'	System	15 Aug 2020 00:43:53
	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96e4a2b6-63fe-42cb-9254-ce6b6dbe511e' User entered 'No (N)'	System	15 Aug 2020 00:43:53
	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:47', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96e4a2b6-63fe-42cb-9254-ce6b6dbe511e' User entered '14 Aug 2020 20:43'	System	15 Aug 2020 00:43:53
	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 3'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:55:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f8b15b7b-4377-406e-923a-64ef3a6e90d2'	System	15 Aug 2020 21:56:11
User entered 'Yes (Y)'	System	15 Aug 2020 21:56:11

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:55:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f8b15b7b-4377-406e-923a-64ef3a6e90d2' User entered '97.7'	System	15 Aug 2020 21:56:11
	System	15 Aug 2020 21:56:11

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f8b15b7b-4377-406e-923a-64ef3a6e90d2'	System	15 Aug 2020 21:56:11
User entered 'No (N)'	System	15 Aug 2020 21:56:11

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f8b15b7b-4377-406e-923a-64ef3a6e90d2'	System	15 Aug 2020 21:56:11
User entered '15 Aug 2020 17:56'	System	15 Aug 2020 21:56:11

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 4'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '097f454f-4a43-42e4-954c-995fdf7226a9' User entered 'Yes (Y)'	System	16 Aug 2020 22:13:24
	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:10', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '097f454f-4a43-42e4-954c-995fdf7226a9' User entered '98.2'	System	16 Aug 2020 22:13:24
	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '097f454f-4a43-42e4-954c-995fdf7226a9' User entered 'No (N)'	System	16 Aug 2020 22:13:24
	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:21', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '097f454f-4a43-42e4-954c-995fdf7226a9' User entered '16 Aug 2020 18:13'	System	16 Aug 2020 22:13:24
	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 5'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:38:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a7390ae-c2d6-4f49-a217-a21bceee0aa9' User entered 'Yes (Y)'	System	17 Aug 2020 22:38:56
	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:38:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a7390ae-c2d6-4f49-a217-a21bceee0aa9' User entered '98.5'	System	17 Aug 2020 22:38:56
	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:38:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a7390ae-c2d6-4f49-a217-a21bceee0aa9' User entered 'No (N)'	System	17 Aug 2020 22:38:56
	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:38:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a7390ae-c2d6-4f49-a217-a21bceee0aa9' User entered '17 Aug 2020 18:38'	System	17 Aug 2020 22:38:56
	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 6'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff7e17d7-57fd-4edd-9950-107d9bf2b304'	System	18 Aug 2020 23:53:03
User entered 'Yes (Y)'	System	18 Aug 2020 23:53:03

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:51', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff7e17d7-57fd-4edd-9950-107d9bf2b304' User entered '97.9'	System	18 Aug 2020 23:53:03
	System	18 Aug 2020 23:53:03

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:55', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff7e17d7-57fd-4edd-9950-107d9bf2b304'	System	18 Aug 2020 23:53:03
User entered 'No (N)'	System	18 Aug 2020 23:53:03

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff7e17d7-57fd-4edd-9950-107d9bf2b304'	System	18 Aug 2020 23:53:03
User entered '18 Aug 2020 19:52'	System	18 Aug 2020 23:53:03

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 7'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:02:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd4c6251b-e9bb-4e30-bb01-08d70792e2c0' User entered 'Yes (Y)'	System	19 Aug 2020 23:02:15
	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:02:06', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd4c6251b-e9bb-4e30-bb01-08d70792e2c0' User entered '97.5'	System	19 Aug 2020 23:02:15
	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:02:09', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd4c6251b-e9bb-4e30-bb01-08d70792e2c0'	System	19 Aug 2020 23:02:15
User entered 'No (N)'	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:02:13', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd4c6251b-e9bb-4e30-bb01-08d70792e2c0'	System	19 Aug 2020 23:02:15
User entered '19 Aug 2020 19:02'	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd3630cdc-4c16-4f24-826a-8469413c42ef' User entered 'None (1)'	System	13 Aug 2020 17:26:50
	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd3630cdc-4c16-4f24-826a-8469413c42ef' User entered 'No (N)'	System	13 Aug 2020 17:26:50
	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd3630cdc-4c16-4f24-826a-8469413c42ef' User entered 'No (N)'	System	13 Aug 2020 17:26:50
	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd3630cdc-4c16-4f24-826a-8469413c42ef' User entered 'None (1)'	System	13 Aug 2020 17:26:50
	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd3630cdc-4c16-4f24-826a-8469413c42ef' User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:26:50
	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 13:08'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 15:38'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:17:51', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a3b305b5-cce9-491b-8aad-3384fc1afa5d'	System	14 Aug 2020 14:18:11
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:16:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a3b305b5-cce9-491b-8aad-3384fc1afa5d' User entered 'No (N)'	System	14 Aug 2020 14:18:11
	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:16:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a3b305b5-cce9-491b-8aad-3384fc1afa5d' User entered 'No (N)'	System	14 Aug 2020 14:18:11
	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:17:32', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a3b305b5-cce9-491b-8aad-3384fc1afa5d'	System	14 Aug 2020 14:18:11
User entered 'None (1)'	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a3b305b5-cce9-491b-8aad-3384fc1afa5d' User entered '14 Aug 2020 10:18'	System	14 Aug 2020 14:18:11
	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 16:33'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 2'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:56', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd'	System	15 Aug 2020 00:45:50
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:43:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd' User entered 'No (N)'	System	15 Aug 2020 00:45:50
	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:44:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd' User entered 'Yes (Y)'	System	15 Aug 2020 00:45:50
	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:45:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd' User entered '1'	System	15 Aug 2020 00:45:50
	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:45:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd'	System	15 Aug 2020 00:45:50
User entered 'None (1)'	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:45:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4e7327f9-5c30-449c-b6ac-98612dbce1dd' User entered '14 Aug 2020 20:45'	System	15 Aug 2020 00:45:50
	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 3'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:16', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7'	System	15 Aug 2020 21:57:16
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7'	System	15 Aug 2020 21:57:16
User entered 'No (N)'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7'	System	15 Aug 2020 21:57:16
User entered 'Yes (Y)'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:56:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7'	System	15 Aug 2020 21:57:16
User entered '1'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7' User entered 'None (1)'	System	15 Aug 2020 21:57:16
	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '031bf072-bba4-4c56-b942-551aed3964a7'	System	15 Aug 2020 21:57:16
User entered '15 Aug 2020 17:57'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 4'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:12:10', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2adeb708-809e-4ac3-a583-0afd21eacff1'	System	16 Aug 2020 22:12:58
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 22:12:58

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:12:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2adeb708-809e-4ac3-a583-0afd21eacff1' User entered 'No (N)'	System	16 Aug 2020 22:12:58
	System	16 Aug 2020 22:12:58

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:12:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2adeb708-809e-4ac3-a583-0afd21eacff1'	System	16 Aug 2020 22:12:58
User entered 'No (N)'	System	16 Aug 2020 22:12:58

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:12:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2adeb708-809e-4ac3-a583-0afd21eacff1'	System	16 Aug 2020 22:12:58
User entered 'None (1)'	System	16 Aug 2020 22:12:58

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:12:55', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2adeb708-809e-4ac3-a583-0afd21eacff1'	System	16 Aug 2020 22:12:58
User entered '16 Aug 2020 18:12'	System	16 Aug 2020 22:12:58

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 5'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8eee23cb-41df-4054-ad5e-f682fa2f5a7d'	System	17 Aug 2020 22:39:48
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:11', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8eee23cb-41df-4054-ad5e-f682fa2f5a7d' User entered 'No (N)'	System	17 Aug 2020 22:39:48
	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8eee23cb-41df-4054-ad5e-f682fa2f5a7d' User entered 'No (N)'	System	17 Aug 2020 22:39:48
	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8eee23cb-41df-4054-ad5e-f682fa2f5a7d' User entered 'None (1)'	System	17 Aug 2020 22:39:48
	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8eee23cb-41df-4054-ad5e-f682fa2f5a7d' User entered '17 Aug 2020 18:39'	System	17 Aug 2020 22:39:48
	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 6'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:51:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6c1bf2fe-7de4-4ee1-878e-b85d4293069f'	System	18 Aug 2020 23:51:57
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:51:32', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6c1bf2fe-7de4-4ee1-878e-b85d4293069f' User entered 'No (N)'	System	18 Aug 2020 23:51:57
	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:51:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6c1bf2fe-7de4-4ee1-878e-b85d4293069f' User entered 'No (N)'	System	18 Aug 2020 23:51:57
	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:51:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6c1bf2fe-7de4-4ee1-878e-b85d4293069f' User entered 'None (1)'	System	18 Aug 2020 23:51:57
	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:51:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6c1bf2fe-7de4-4ee1-878e-b85d4293069f' User entered '18 Aug 2020 19:51'	System	18 Aug 2020 23:51:57
	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 7'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:00:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '64d95025-2958-497b-8084-fceef8c392c'	System	19 Aug 2020 23:01:03
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:00:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '64d95025-2958-497b-8084-fceef8c392c' User entered 'No (N)'	System	19 Aug 2020 23:01:03
	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:00:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '64d95025-2958-497b-8084-fceef8c392c'	System	19 Aug 2020 23:01:03
User entered 'No (N)'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:00:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '64d95025-2958-497b-8084-fceef8c392c'	System	19 Aug 2020 23:01:03
User entered 'None (1)'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '64d95025-2958-497b-8084-fceef8c392c' User entered '19 Aug 2020 19:01'	System	19 Aug 2020 23:01:03
	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:26:58', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:02', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:11', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:28', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered 'No (N)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-13T13:27:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c8391946-7843-4c5c-996f-9c744de3ae00' User entered '13 Aug 2020 13:27'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 13:08'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 15:38'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3'	System	14 Aug 2020 14:19:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3'	System	14 Aug 2020 14:19:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered 'None (0)'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered 'None (0)'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered 'None (0)'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:18:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered 'None (0)'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:19:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered 'No (N)'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T10:19:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ed0f73ce-48e0-412e-8634-125a1cac38a3' User entered '14 Aug 2020 10:19'	System	14 Aug 2020 14:19:39
	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Aug 2020 16:33'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 2'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:45:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d'	System	15 Aug 2020 00:48:38
User entered 'No interference with activity (1)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:47:47', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d'	System	15 Aug 2020 00:48:38
User entered 'Some interference with activity (2)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered 'None (0)'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered 'None (0)'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:06', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered 'None (0)'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:09', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered 'None (0)'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered 'No (N)'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-14T20:48:24', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '574070b1-2444-4891-91dc-23e48ad7eb8d' User entered '14 Aug 2020 20:48'	System	15 Aug 2020 00:48:38
	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 3'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:21', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered 'None (0)'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:57:53', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9'	System	15 Aug 2020 21:58:08
User entered 'No (N)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-15T17:58:05', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a9b58056-6ad9-43d4-84df-d83b2464eee9' User entered '15 Aug 2020 17:58'	System	15 Aug 2020 21:58:08
	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 4'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:28', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'None (0)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:49', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered 'No (N)'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-16T18:13:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b102570a-3b31-486c-b299-6bb4236d91b9' User entered '16 Aug 2020 18:13'	System	16 Aug 2020 22:13:58
	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 5'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842'	System	17 Aug 2020 22:40:17
User entered 'None (0)'	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:52', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842' User entered 'None (0)'	System	17 Aug 2020 22:40:17
	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:55', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842' User entered 'None (0)'	System	17 Aug 2020 22:40:17
	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:39:58', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842' User entered 'None (0)'	System	17 Aug 2020 22:40:17
	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:40:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842' User entered 'None (0)'	System	17 Aug 2020 22:40:17
	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:40:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842' User entered 'None (0)'	System	17 Aug 2020 22:40:17
	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:40:09', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842'	System	17 Aug 2020 22:40:17
User entered 'No (N)'	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-17T18:40:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ea3df0a-7b1c-4887-8ee1-69e647c50842'	System	17 Aug 2020 22:40:17
User entered '17 Aug 2020 18:40'	System	17 Aug 2020 22:40:17

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 6'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:06', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:09', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'None (0)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:28', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered 'No (N)'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-18T19:52:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bacb5af-1ffa-4134-9709-1e0de6ee768e' User entered '18 Aug 2020 19:52'	System	18 Aug 2020 23:52:37
	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 7'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:09', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'None (0)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered 'No (N)'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-19T19:01:28', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16ae846d-dde9-4506-a494-6f9c5fc03639' User entered '19 Aug 2020 19:01'	System	19 Aug 2020 23:01:30
	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	18 Aug 2020 23:51:57
User entered 'Day 8'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-21T00:26:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1f468559-0928-4217-89ed-df4c075cb3c5'	System	21 Aug 2020 04:26:54
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-21T00:26:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1f468559-0928-4217-89ed-df4c075cb3c5' User entered '21 Aug 2020 00:26'	System	21 Aug 2020 04:26:54
	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Aug 2020 23:01:03
User entered 'Day 9'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-22T00:04:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '01b123af-7e71-4ab2-899c-093187e9019b'	System	22 Aug 2020 04:04:50
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-22T00:04:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '01b123af-7e71-4ab2-899c-093187e9019b' User entered '22 Aug 2020 00:04'	System	22 Aug 2020 04:04:50
	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	21 Aug 2020 04:26:54
User entered 'Day 10'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-23T08:22:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '995883d9-6f4e-4ea9-98d2-cce9773db16b' User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 12:22:39
	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-23T08:22:36', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '995883d9-6f4e-4ea9-98d2-cce9773db16b' User entered '23 Aug 2020 08:22'	System	23 Aug 2020 12:22:39
	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	22 Aug 2020 04:04:50
User entered 'Day 11'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T00:58:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4439df95-6268-4876-919c-d0bb4c7e73fa'	System	24 Aug 2020 04:58:22
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T00:58:21', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4439df95-6268-4876-919c-d0bb4c7e73fa' User entered '24 Aug 2020 00:58'	System	24 Aug 2020 04:58:22
	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	23 Aug 2020 12:22:39
User entered 'Day 12'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T22:23:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0ab3f31-ddc9-46bd-b51b-b5c2fdeaf61b' User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 02:23:47
	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T22:23:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0ab3f31-ddc9-46bd-b51b-b5c2fdeaf61b' User entered '24 Aug 2020 22:23'	System	25 Aug 2020 02:23:47
	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	24 Aug 2020 04:58:22
User entered 'Day 13'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T00:34:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0a02702e-77fb-4b48-9df0-40cee9201c98'	System	26 Aug 2020 04:38:53
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T00:34:21', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0a02702e-77fb-4b48-9df0-40cee9201c98' User entered '26 Aug 2020 00:34'	System	26 Aug 2020 04:38:53
	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Aug 2020 02:23:47
User entered 'Day 14'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T21:10:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c6cf18db-81e6-4e89-b8a8-61af6e772214'	System	27 Aug 2020 01:11:06
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T21:10:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c6cf18db-81e6-4e89-b8a8-61af6e772214' User entered '26 Aug 2020 21:10'	System	27 Aug 2020 01:11:06
	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	26 Aug 2020 04:38:53
User entered 'Day 15'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-27T21:00:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1b89e668-a501-401a-9617-9be12ba18106'	System	28 Aug 2020 01:00:37
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-27T21:00:32', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1b89e668-a501-401a-9617-9be12ba18106'	System	28 Aug 2020 01:00:37
User entered '27 Aug 2020 21:00'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	27 Aug 2020 01:11:06
User entered 'Day 16'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-28T23:11:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '830ff768-c138-47df-902a-f987f9889992'	System	29 Aug 2020 03:11:30
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-28T23:11:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '830ff768-c138-47df-902a-f987f9889992'	System	29 Aug 2020 03:11:30
User entered '28 Aug 2020 23:11'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	28 Aug 2020 01:00:37
User entered 'Day 17'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T01:19:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b5c70105-48ff-4c04-9bb0-bb5662ad8149'	System	30 Aug 2020 05:19:26
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T01:19:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b5c70105-48ff-4c04-9bb0-bb5662ad8149' User entered '30 Aug 2020 01:19'	System	30 Aug 2020 05:19:26
	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	29 Aug 2020 03:11:30
User entered 'Day 18'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T19:24:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4dbed686-deef-4fe9-adfc-928ea233f6e9'	System	30 Aug 2020 23:24:46
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T19:24:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '4dbed686-deef-4fe9-adfc-928ea233f6e9' User entered '30 Aug 2020 19:24'	System	30 Aug 2020 23:24:46
	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	30 Aug 2020 05:19:26
User entered 'Day 19'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-31T23:54:27', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a4c2ffaf-6cb8-4a1d-83ce-60d14ed190e8'	System	01 Sep 2020 03:54:32
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-31T23:54:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a4c2ffaf-6cb8-4a1d-83ce-60d14ed190e8'	System	01 Sep 2020 03:54:32
User entered '31 Aug 2020 23:54'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	30 Aug 2020 23:24:46
User entered 'Day 20'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-01T23:07:56', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b5caf943-339f-4b7c-ae11-888318acdf62'	System	02 Sep 2020 03:08:00
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-01T23:07:58', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b5caf943-339f-4b7c-ae11-888318acdf62'	System	02 Sep 2020 03:08:00
User entered '01 Sep 2020 23:07'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Sep 2020 03:54:32
User entered 'Day 21'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-02T17:05:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '33d878d0-5eca-44af-9e93-94bcab830c71'	System	02 Sep 2020 21:05:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-02T17:05:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '33d878d0-5eca-44af-9e93-94bcab830c71' User entered '02 Sep 2020 17:05'	System	02 Sep 2020 21:05:26
	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	02 Sep 2020 03:08:00
User entered 'Day 22'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-03T20:53:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2a86f21f-f04a-4848-b0c0-37abf9483e6b'	System	04 Sep 2020 00:53:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-03T20:53:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2a86f21f-f04a-4848-b0c0-37abf9483e6b' User entered '03 Sep 2020 20:53'	System	04 Sep 2020 00:53:41
	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	02 Sep 2020 21:05:26
User entered 'Day 23'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Sep 2020 00:53:41
User entered 'Day 24'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-05T16:50:16', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '25c6ccfe-7a40-4334-9b29-49cbfa75986c'	System	05 Sep 2020 20:50:24
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-05T16:50:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '25c6ccfe-7a40-4334-9b29-49cbfa75986c' User entered '05 Sep 2020 16:50'	System	05 Sep 2020 20:50:24
	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	05 Sep 2020 20:50:24
User entered 'Day 25'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-06T20:15:06', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '499e0577-f1fd-40cf-9bdf-cb51aacb31b7'	System	07 Sep 2020 00:15:14
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-06T20:15:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '499e0577-f1fd-40cf-9bdf-cb51aacb31b7'	System	07 Sep 2020 00:15:14
User entered '06 Sep 2020 20:15'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	05 Sep 2020 20:50:24
User entered 'Day 26'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-08T02:05:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd8bd7187-38c2-4120-9bde-8632bba3ba8e'	System	08 Sep 2020 06:05:35
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-08T02:05:31', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd8bd7187-38c2-4120-9bde-8632bba3ba8e' User entered '08 Sep 2020 02:05'	System	08 Sep 2020 06:05:35
	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Sep 2020 00:15:14
User entered 'Day 27'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T00:49:13', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b23b5637-f518-46f9-b46d-1d09d25b06e5'	System	09 Sep 2020 04:49:17
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T00:49:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b23b5637-f518-46f9-b46d-1d09d25b06e5' User entered '09 Sep 2020 00:49'	System	09 Sep 2020 04:49:17
	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	08 Sep 2020 06:05:35
User entered 'Day 28'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T14:20:31', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8c23c41f-675a-40f3-a5ed-75dfc1e2791c'	System	09 Sep 2020 18:20:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T14:20:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8c23c41f-675a-40f3-a5ed-75dfc1e2791c' User entered '09 Sep 2020 14:20'	System	09 Sep 2020 18:20:37
	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	09 Sep 2020 04:49:17
User entered 'Day 29'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-10T13:38:02', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd2ebe35e-8729-45a9-a02d-4d918f1c8776'	System	10 Sep 2020 17:38:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-10T13:38:05', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd2ebe35e-8729-45a9-a02d-4d918f1c8776' User entered '10 Sep 2020 13:38'	System	10 Sep 2020 17:38:09
	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	09 Sep 2020 18:20:37
User entered 'Day 30'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-11T15:42:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'fc870682-b9e1-4950-81b5-4161ff9c49eb'	System	11 Sep 2020 19:42:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-11T15:42:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'fc870682-b9e1-4950-81b5-4161ff9c49eb' User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:42
	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	10 Sep 2020 17:38:09
User entered 'Day 31'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-12T22:48:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '28d2dee3-8308-4734-a4ab-051460e5e637'	System	13 Sep 2020 02:48:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-12T22:48:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '28d2dee3-8308-4734-a4ab-051460e5e637' User entered '12 Sep 2020 22:48'	System	13 Sep 2020 02:48:22
	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	11 Sep 2020 19:42:42
User entered 'Day 32'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-13T18:41:31', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '605efdba-a897-460a-a900-3a0a68c76b63'	System	13 Sep 2020 22:41:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-13T18:41:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '605efdba-a897-460a-a900-3a0a68c76b63' User entered '13 Sep 2020 18:41'	System	13 Sep 2020 22:41:41
	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Sep 2020 02:48:22
User entered 'Day 33'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-14T14:02:13', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6255003a-72c1-48f7-a7b5-0664c9788730'	System	14 Sep 2020 18:02:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-14T14:02:16', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6255003a-72c1-48f7-a7b5-0664c9788730' User entered '14 Sep 2020 14:02'	System	14 Sep 2020 18:02:19
	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Sep 2020 22:41:41
User entered 'Day 34'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-15T12:44:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f131fe72-b750-458f-9800-04ff55a2f3d7'	System	15 Sep 2020 16:44:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-15T12:44:47', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f131fe72-b750-458f-9800-04ff55a2f3d7'	System	15 Sep 2020 16:44:52
User entered '15 Sep 2020 12:44'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	14 Sep 2020 18:02:19
User entered 'Day 35'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-16T13:46:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '057ec4b0-c45f-4e70-97c0-ccebc64a8d03'	System	16 Sep 2020 17:46:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-16T13:46:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '057ec4b0-c45f-4e70-97c0-ccebc64a8d03' User entered '16 Sep 2020 13:46'	System	16 Sep 2020 17:46:39
	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	15 Sep 2020 16:44:52
User entered 'Day 36'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-17T17:42:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bcddb89c-3e1e-43e2-aba0-26416c3d9175'	System	17 Sep 2020 21:42:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-17T17:42:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'bcddb89c-3e1e-43e2-aba0-26416c3d9175' User entered '17 Sep 2020 17:42'	System	17 Sep 2020 21:42:53
	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	16 Sep 2020 17:46:39
User entered 'Day 37'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-18T23:07:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'eae36520-c481-45b4-a67b-9fd33b2c1c3f'	System	19 Sep 2020 03:07:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-18T23:07:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'eae36520-c481-45b4-a67b-9fd33b2c1c3f' User entered '18 Sep 2020 23:07'	System	19 Sep 2020 03:07:29
	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	17 Sep 2020 21:42:53
User entered 'Day 38'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-19T16:47:56', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd1de6a9d-b55a-4fc7-938b-fc607757761f'	System	19 Sep 2020 20:48:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-19T16:47:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd1de6a9d-b55a-4fc7-938b-fc607757761f' User entered '19 Sep 2020 16:47'	System	19 Sep 2020 20:48:04
	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Sep 2020 03:07:29
User entered 'Day 39'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-21T00:33:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8c8c3009-1b55-446e-b6c0-3ad24752adb8'	System	21 Sep 2020 04:33:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-21T00:33:21', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '8c8c3009-1b55-446e-b6c0-3ad24752adb8' User entered '21 Sep 2020 00:33'	System	21 Sep 2020 04:33:23
	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Sep 2020 20:48:04
User entered 'Day 40'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-22T08:36:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e3b396e6-92a4-4b03-a38d-6ff6e970f344'	System	22 Sep 2020 12:36:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-22T08:36:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e3b396e6-92a4-4b03-a38d-6ff6e970f344'	System	22 Sep 2020 12:36:25
User entered '22 Sep 2020 08:36'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	21 Sep 2020 04:33:23
User entered 'Day 41'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T11:34:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e1f494ba-5dbf-4b4c-a138-11121dff43c5'	System	23 Sep 2020 15:34:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T11:34:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e1f494ba-5dbf-4b4c-a138-11121dff43c5' User entered '23 Sep 2020 11:34'	System	23 Sep 2020 15:34:52
	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	22 Sep 2020 12:36:25
User entered 'Day 42'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T21:59:55', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c25f0e36-eb32-4f1c-b80f-de795bf8b6ae'	System	24 Sep 2020 01:59:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T21:59:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'c25f0e36-eb32-4f1c-b80f-de795bf8b6ae'	System	24 Sep 2020 01:59:59
User entered '23 Sep 2020 21:59'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	23 Sep 2020 15:34:52
User entered 'Day 43'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	24 Sep 2020 01:59:59
User entered 'Day 44'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-25T14:32:16', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '11ded7e0-9ee6-4808-9abf-a9de3960297e'	System	25 Sep 2020 18:32:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-25T14:32:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '11ded7e0-9ee6-4808-9abf-a9de3960297e' User entered '25 Sep 2020 14:32'	System	25 Sep 2020 18:32:23
	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Sep 2020 18:32:23
User entered 'Day 45'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-26T12:48:16', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9383b748-4d24-4789-b6dd-e59f61e5d80a'	System	26 Sep 2020 16:48:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-26T12:48:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9383b748-4d24-4789-b6dd-e59f61e5d80a' User entered '26 Sep 2020 12:48'	System	26 Sep 2020 16:48:22
	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Sep 2020 18:32:23
User entered 'Day 46'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-27T16:29:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b9104e3b-462f-4df0-9e87-958a70523deb'	System	27 Sep 2020 20:29:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-27T16:29:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'b9104e3b-462f-4df0-9e87-958a70523deb' User entered '27 Sep 2020 16:29'	System	27 Sep 2020 20:29:22
	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	26 Sep 2020 16:48:22
User entered 'Day 47'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-28T17:20:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5357f66b-cdf6-4c4f-8876-6765fba0a794'	System	28 Sep 2020 21:20:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-28T17:20:25', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5357f66b-cdf6-4c4f-8876-6765fba0a794' User entered '28 Sep 2020 17:20'	System	28 Sep 2020 21:20:30
	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	27 Sep 2020 20:29:22
User entered 'Day 48'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	28 Sep 2020 21:20:30
User entered 'Day 49'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-30T19:23:47', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '952a4ec5-1efa-488a-98b7-bfc68c2cac5c'	System	01 Oct 2020 00:23:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-30T19:23:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '952a4ec5-1efa-488a-98b7-bfc68c2cac5c' User entered '30 Sep 2020 19:23'	System	01 Oct 2020 00:23:52
	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 00:23:52
User entered 'Day 50'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-01T18:03:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a2208b25-6f43-4e03-8b16-f1551a6e2662'	System	01 Oct 2020 23:03:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-01T18:03:10', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a2208b25-6f43-4e03-8b16-f1551a6e2662' User entered '01 Oct 2020 18:03'	System	01 Oct 2020 23:03:12
	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 00:23:52
User entered 'Day 51'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T11:53:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a9838f2-927c-483b-9782-5a3efffb1025'	System	03 Oct 2020 16:53:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T11:53:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9a9838f2-927c-483b-9782-5a3efffb1025' User entered '03 Oct 2020 11:53'	System	03 Oct 2020 16:53:29
	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 23:03:12
User entered 'Day 52'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T19:17:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0a11d4e-dd79-4159-b79d-ea22393f5f83'	System	04 Oct 2020 00:17:57
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T19:17:53', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f0a11d4e-dd79-4159-b79d-ea22393f5f83' User entered '03 Oct 2020 19:17'	System	04 Oct 2020 00:17:57
	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	03 Oct 2020 16:53:29
User entered 'Day 53'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-04T15:19:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5f63d819-2fd4-4b6b-aec6-5384cc8f0f56'	System	04 Oct 2020 20:19:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-04T15:19:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5f63d819-2fd4-4b6b-aec6-5384cc8f0f56' User entered '04 Oct 2020 15:19'	System	04 Oct 2020 20:19:49
	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Oct 2020 00:17:57
User entered 'Day 54'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Oct 2020 20:19:49
User entered 'Day 55'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-06T23:09:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '61cc3a79-0920-452d-bdcd-39ca1866b088'	System	07 Oct 2020 04:09:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-06T23:09:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '61cc3a79-0920-452d-bdcd-39ca1866b088' User entered '06 Oct 2020 23:09'	System	07 Oct 2020 04:09:19
	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Oct 2020 04:09:19
User entered 'Day 56'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Oct 2020 04:09:19
User entered 'Day 57'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	18 Aug 2020 23:51:57
User entered 'Day 8'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-21T00:28:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ec494218-0890-47d5-8149-4c061e8ea7a5'	System	21 Aug 2020 04:28:34
User entered 'No (N)'	System	21 Aug 2020 04:28:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-21T00:28:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ec494218-0890-47d5-8149-4c061e8ea7a5' User entered '21 Aug 2020 00:28'	System	21 Aug 2020 04:28:34
	System	21 Aug 2020 04:28:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Aug 2020 23:01:03
User entered 'Day 9'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-22T00:04:51', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '93acd47d-da94-4224-9e5f-8f3b9e49d467'	System	22 Aug 2020 04:04:56
User entered 'No (N)'	System	22 Aug 2020 04:04:56

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-22T00:04:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '93acd47d-da94-4224-9e5f-8f3b9e49d467'	System	22 Aug 2020 04:04:56
User entered '22 Aug 2020 00:04'	System	22 Aug 2020 04:04:56

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	21 Aug 2020 04:26:54
User entered 'Day 10'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-23T08:22:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6a798137-5f18-4670-8a60-7fae4eb88067' User entered 'No (N)'	System	23 Aug 2020 12:22:45
	System	23 Aug 2020 12:22:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-23T08:22:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6a798137-5f18-4670-8a60-7fae4eb88067' User entered '23 Aug 2020 08:22'	System	23 Aug 2020 12:22:45
	System	23 Aug 2020 12:22:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	22 Aug 2020 04:04:50
User entered 'Day 11'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T00:58:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '79991ff3-1d9c-4ad4-84c3-7278633efe8d' User entered 'No (N)'	System	24 Aug 2020 04:58:37
	System	24 Aug 2020 04:58:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T00:58:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '79991ff3-1d9c-4ad4-84c3-7278633efe8d' User entered '24 Aug 2020 00:58'	System	24 Aug 2020 04:58:37
	System	24 Aug 2020 04:58:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	23 Aug 2020 12:22:39
User entered 'Day 12'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T22:23:53', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '90b87496-de6b-4be9-933c-024c50f434bc' User entered 'No (N)'	System	25 Aug 2020 02:23:58
	System	25 Aug 2020 02:23:58

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-24T22:23:56', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '90b87496-de6b-4be9-933c-024c50f434bc' User entered '24 Aug 2020 22:23'	System	25 Aug 2020 02:23:58
	System	25 Aug 2020 02:23:58

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	24 Aug 2020 04:58:22
User entered 'Day 13'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T00:34:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '62ddc12e-088a-4a1d-89dd-5235cdc40beb' User entered 'No (N)'	System	26 Aug 2020 04:38:57
	System	26 Aug 2020 04:38:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T00:34:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '62ddc12e-088a-4a1d-89dd-5235cdc40beb' User entered '26 Aug 2020 00:34'	System	26 Aug 2020 04:38:57
	System	26 Aug 2020 04:38:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Aug 2020 02:23:47
User entered 'Day 14'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T21:10:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5f4c1ca1-bb96-4149-906d-7742c9e0297b' User entered 'No (N)'	System	27 Aug 2020 01:11:10
	System	27 Aug 2020 01:11:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-26T21:10:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5f4c1ca1-bb96-4149-906d-7742c9e0297b' User entered '26 Aug 2020 21:10'	System	27 Aug 2020 01:11:10
	System	27 Aug 2020 01:11:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	26 Aug 2020 04:38:53
User entered 'Day 15'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-27T21:00:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd63f415d-b884-4845-8c53-371636017de1' User entered 'No (N)'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-27T21:00:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd63f415d-b884-4845-8c53-371636017de1' User entered '27 Aug 2020 21:00'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	27 Aug 2020 01:11:06
User entered 'Day 16'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-28T23:11:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16992db1-814b-4f9d-8e4f-6af7b88d0dc9' User entered 'No (N)'	System	29 Aug 2020 03:11:35
	System	29 Aug 2020 03:11:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-28T23:11:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '16992db1-814b-4f9d-8e4f-6af7b88d0dc9' User entered '28 Aug 2020 23:11'	System	29 Aug 2020 03:11:35
	System	29 Aug 2020 03:11:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	28 Aug 2020 01:00:37
User entered 'Day 17'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T01:19:27', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '997125ba-afe2-4d1d-9868-2580e1526e26' User entered 'No (N)'	System	30 Aug 2020 05:19:34
	System	30 Aug 2020 05:19:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T01:19:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '997125ba-afe2-4d1d-9868-2580e1526e26' User entered '30 Aug 2020 01:19'	System	30 Aug 2020 05:19:34
	System	30 Aug 2020 05:19:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:00:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	29 Aug 2020 03:11:30
User entered 'Day 18'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T19:24:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0f479c03-d67e-4503-8387-576bf70db1d2'	System	30 Aug 2020 23:24:48
User entered 'No (N)'	System	30 Aug 2020 23:24:48

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-30T19:24:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0f479c03-d67e-4503-8387-576bf70db1d2'	System	30 Aug 2020 23:24:48
User entered '30 Aug 2020 19:24'	System	30 Aug 2020 23:24:48

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:11:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	30 Aug 2020 05:19:26
User entered 'Day 19'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-31T23:54:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ddbEEba5-0658-4790-bbf2-0d64b781b347' User entered 'No (N)'	System	01 Sep 2020 03:54:42
	System	01 Sep 2020 03:54:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-08-31T23:54:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ddbEEba5-0658-4790-bbf2-0d64b781b347'	System	01 Sep 2020 03:54:42
User entered '31 Aug 2020 23:54'	System	01 Sep 2020 03:54:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	30 Aug 2020 23:24:46
User entered 'Day 20'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-01T23:08:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd321a92d-0ce1-4616-ac68-bbc425f985fb' User entered 'No (N)'	System	02 Sep 2020 03:08:11
	System	02 Sep 2020 03:08:11

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-01T23:08:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd321a92d-0ce1-4616-ac68-bbc425f985fb' User entered '01 Sep 2020 23:08'	System	02 Sep 2020 03:08:11
	System	02 Sep 2020 03:08:11

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Sep 2020 03:54:32
User entered 'Day 21'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-02T17:05:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'fa7c2f4f-6b06-44ad-839d-df530e11f189'	System	02 Sep 2020 21:05:31
User entered 'No (N)'	System	02 Sep 2020 21:05:31

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-02T17:05:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'fa7c2f4f-6b06-44ad-839d-df530e11f189'	System	02 Sep 2020 21:05:31
User entered '02 Sep 2020 17:05'	System	02 Sep 2020 21:05:31

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 03:54:32

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	02 Sep 2020 03:08:00
User entered 'Day 22'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-03T20:53:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2f68a6ec-712a-4b5c-b183-46376735ee6d' User entered 'No (N)'	System	04 Sep 2020 00:53:51
	System	04 Sep 2020 00:53:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-03T20:53:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2f68a6ec-712a-4b5c-b183-46376735ee6d' User entered '03 Sep 2020 20:53'	System	04 Sep 2020 00:53:51
	System	04 Sep 2020 00:53:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 03:08:00

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	02 Sep 2020 21:05:26
User entered 'Day 23'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Sep 2020 00:53:41
User entered 'Day 24'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-05T16:50:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '814bf9bf-2691-4ff9-9be0-690f0b5049f6'	System	05 Sep 2020 20:50:29
User entered 'No (N)'	System	05 Sep 2020 20:50:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-05T16:50:25', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '814bf9bf-2691-4ff9-9be0-690f0b5049f6' User entered '05 Sep 2020 16:50'	System	05 Sep 2020 20:50:29
	System	05 Sep 2020 20:50:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	05 Sep 2020 20:50:24
User entered 'Day 25'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-06T20:15:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a55539c6-b066-4ccc-9738-a7c68f608a9b' User entered 'No (N)'	System	07 Sep 2020 00:15:17
	System	07 Sep 2020 00:15:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-06T20:15:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'a55539c6-b066-4ccc-9738-a7c68f608a9b' User entered '06 Sep 2020 20:15'	System	07 Sep 2020 00:15:17
	System	07 Sep 2020 00:15:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	05 Sep 2020 20:50:24
User entered 'Day 26'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-08T02:05:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '17e09bca-3bba-411b-81a2-f55f7ab9627c' User entered 'No (N)'	System	08 Sep 2020 06:05:40
	System	08 Sep 2020 06:05:40

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-08T02:05:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '17e09bca-3bba-411b-81a2-f55f7ab9627c' User entered '08 Sep 2020 02:05'	System	08 Sep 2020 06:05:40
	System	08 Sep 2020 06:05:40

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Sep 2020 00:15:14
User entered 'Day 27'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T00:49:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '30748c9b-0ba4-413b-b00e-e77895d48428' User entered 'No (N)'	System	09 Sep 2020 04:49:26
	System	09 Sep 2020 04:49:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T00:49:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '30748c9b-0ba4-413b-b00e-e77895d48428' User entered '09 Sep 2020 00:49'	System	09 Sep 2020 04:49:26
	System	09 Sep 2020 04:49:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 00:15:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	08 Sep 2020 06:05:35
User entered 'Day 28'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T14:20:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0a8fd8b7-ba06-4717-bfdb-802c88ae3a18'	System	09 Sep 2020 18:20:44
User entered 'Yes (Y)'	System	09 Sep 2020 18:20:44

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-09T14:20:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0a8fd8b7-ba06-4717-bfdb-802c88ae3a18' User entered '09 Sep 2020 14:20'	System	09 Sep 2020 18:20:44
	System	09 Sep 2020 18:20:44

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	09 Sep 2020 04:49:17
User entered 'Day 29'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-10T13:38:55', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '394b0dc9-1ac0-49f1-9445-b586e4d3312c' User entered 'No (N)'	System	10 Sep 2020 17:39:01
	System	10 Sep 2020 17:39:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-10T13:38:58', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '394b0dc9-1ac0-49f1-9445-b586e4d3312c' User entered '10 Sep 2020 13:38'	System	10 Sep 2020 17:39:01
	System	10 Sep 2020 17:39:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	09 Sep 2020 18:20:37
User entered 'Day 30'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-11T15:42:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f231e3ef-51ed-4b17-9fad-bd9d905e3e14'	System	11 Sep 2020 19:42:51
User entered 'No (N)'	System	11 Sep 2020 19:42:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-11T15:42:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f231e3ef-51ed-4b17-9fad-bd9d905e3e14'	System	11 Sep 2020 19:42:51
User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	10 Sep 2020 17:38:09
User entered 'Day 31'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-12T22:48:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '52fe18c3-0636-4fd0-8fae-096c356f1851' User entered 'No (N)'	System	13 Sep 2020 02:48:29
	System	13 Sep 2020 02:48:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-12T22:48:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '52fe18c3-0636-4fd0-8fae-096c356f1851' User entered '12 Sep 2020 22:48'	System	13 Sep 2020 02:48:29
	System	13 Sep 2020 02:48:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	11 Sep 2020 19:42:42
User entered 'Day 32'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-13T18:41:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '26eff16b-e576-47b3-9fca-313cbd8b0064' User entered 'No (N)'	System	13 Sep 2020 22:41:47
	System	13 Sep 2020 22:41:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-13T18:41:44', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '26eff16b-e576-47b3-9fca-313cbd8b0064' User entered '13 Sep 2020 18:41'	System	13 Sep 2020 22:41:47
	System	13 Sep 2020 22:41:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Sep 2020 02:48:22
User entered 'Day 33'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-14T14:02:25', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6101abce-f1d2-446b-90fc-434847247e72'	System	14 Sep 2020 18:02:32
User entered 'No (N)'	System	14 Sep 2020 18:02:32

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-14T14:02:28', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6101abce-f1d2-446b-90fc-434847247e72'	System	14 Sep 2020 18:02:32
User entered '14 Sep 2020 14:02'	System	14 Sep 2020 18:02:32

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Sep 2020 22:41:41
User entered 'Day 34'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-15T12:45:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '01dd63e7-e685-4079-998e-728c8471fa7b' User entered 'Yes (Y)'	System	15 Sep 2020 16:45:14
	System	15 Sep 2020 16:45:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-15T12:45:11', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '01dd63e7-e685-4079-998e-728c8471fa7b' User entered '15 Sep 2020 12:45'	System	15 Sep 2020 16:45:14
	System	15 Sep 2020 16:45:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	14 Sep 2020 18:02:19
User entered 'Day 35'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-16T13:46:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '45e1eaf1-9a26-4cc9-80b0-59160e372850' User entered 'Yes (Y)'	System	16 Sep 2020 17:46:51
	System	16 Sep 2020 17:46:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-16T13:46:47', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '45e1eaf1-9a26-4cc9-80b0-59160e372850' User entered '16 Sep 2020 13:46'	System	16 Sep 2020 17:46:51
	System	16 Sep 2020 17:46:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	15 Sep 2020 16:44:52
User entered 'Day 36'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-17T17:42:58', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd0d11677-b0c8-4fee-b302-7994969ec625' User entered 'No (N)'	System	17 Sep 2020 21:43:02
	System	17 Sep 2020 21:43:02

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-17T17:43:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'd0d11677-b0c8-4fee-b302-7994969ec625' User entered '17 Sep 2020 17:43'	System	17 Sep 2020 21:43:02
	System	17 Sep 2020 21:43:02

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:44:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	16 Sep 2020 17:46:39
User entered 'Day 37'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-18T23:07:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0bd72959-a8c6-4779-905b-133951f7f7d5' User entered 'No (N)'	System	19 Sep 2020 03:07:42
	System	19 Sep 2020 03:07:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-18T23:07:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0bd72959-a8c6-4779-905b-133951f7f7d5' User entered '18 Sep 2020 23:07'	System	19 Sep 2020 03:07:42
	System	19 Sep 2020 03:07:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	17 Sep 2020 21:42:53
User entered 'Day 38'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-19T16:48:04', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9fe43c4d-00a1-484e-9ae7-09017020e54b' User entered 'No (N)'	System	19 Sep 2020 20:48:10
	System	19 Sep 2020 20:48:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-19T16:48:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9fe43c4d-00a1-484e-9ae7-09017020e54b' User entered '19 Sep 2020 16:48'	System	19 Sep 2020 20:48:10
	System	19 Sep 2020 20:48:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Sep 2020 03:07:29
User entered 'Day 39'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-21T00:33:25', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3c174d29-f9b7-4d9c-a17c-8bd9384bdf7'	System	21 Sep 2020 04:33:30
User entered 'No (N)'	System	21 Sep 2020 04:33:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-21T00:33:27', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3c174d29-f9b7-4d9c-a17c-8bd9384bdf7' User entered '21 Sep 2020 00:33'	System	21 Sep 2020 04:33:30
	System	21 Sep 2020 04:33:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	19 Sep 2020 20:48:04
User entered 'Day 40'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-22T08:36:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '7108cd71-864c-46dc-9fd0-81c8a2019d11'	System	22 Sep 2020 12:36:31
User entered 'No (N)'	System	22 Sep 2020 12:36:31

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-22T08:36:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '7108cd71-864c-46dc-9fd0-81c8a2019d11' User entered '22 Sep 2020 08:36'	System	22 Sep 2020 12:36:31
	System	22 Sep 2020 12:36:31

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	21 Sep 2020 04:33:23
User entered 'Day 41'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T11:34:50', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0ce7f616-6a76-4749-8e90-f7d549c445b1' User entered 'No (N)'	System	23 Sep 2020 15:34:57
	System	23 Sep 2020 15:34:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T11:34:52', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0ce7f616-6a76-4749-8e90-f7d549c445b1' User entered '23 Sep 2020 11:34'	System	23 Sep 2020 15:34:57
	System	23 Sep 2020 15:34:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	22 Sep 2020 12:36:25
User entered 'Day 42'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T22:00:01', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'dabeac6c-a180-40da-8e64-12f19da515f2'	System	24 Sep 2020 02:00:15
User entered 'No (N)'	System	24 Sep 2020 02:00:15

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-23T22:00:03', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'dabeac6c-a180-40da-8e64-12f19da515f2'	System	24 Sep 2020 02:00:15
User entered '23 Sep 2020 22:00'	System	24 Sep 2020 02:00:15

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 12:36:25

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	23 Sep 2020 15:34:52
User entered 'Day 43'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	24 Sep 2020 01:59:59
User entered 'Day 44'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-25T14:32:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff8c3b0f-1b70-444b-ba27-2dd708be67c2'	System	25 Sep 2020 18:32:29
User entered 'No (N)'	System	25 Sep 2020 18:32:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-25T14:32:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'ff8c3b0f-1b70-444b-ba27-2dd708be67c2' User entered '25 Sep 2020 14:32'	System	25 Sep 2020 18:32:29
	System	25 Sep 2020 18:32:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:59:59

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Sep 2020 18:32:23
User entered 'Day 45'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-26T12:48:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5955ae21-543e-4dd0-bde4-cefcfb204758' User entered 'No (N)'	System	26 Sep 2020 16:48:26
	System	26 Sep 2020 16:48:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-26T12:48:24', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5955ae21-543e-4dd0-bde4-cefcfb204758' User entered '26 Sep 2020 12:48'	System	26 Sep 2020 16:48:26
	System	26 Sep 2020 16:48:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	25 Sep 2020 18:32:23
User entered 'Day 46'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-27T16:29:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f1013fb5-2cc7-483d-bc86-b310334e1c71' User entered 'No (N)'	System	27 Sep 2020 20:29:29
	System	27 Sep 2020 20:29:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-27T16:29:25', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f1013fb5-2cc7-483d-bc86-b310334e1c71' User entered '27 Sep 2020 16:29'	System	27 Sep 2020 20:29:29
	System	27 Sep 2020 20:29:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:32:23

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	26 Sep 2020 16:48:22
User entered 'Day 47'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-28T17:20:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6d4928b1-b98d-4f21-b524-6f750bbe33fa' User entered 'No (N)'	System	28 Sep 2020 21:20:35
	System	28 Sep 2020 21:20:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-28T17:20:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6d4928b1-b98d-4f21-b524-6f750bbe33fa' User entered '28 Sep 2020 17:20'	System	28 Sep 2020 21:20:35
	System	28 Sep 2020 21:20:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	27 Sep 2020 20:29:22
User entered 'Day 48'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	28 Sep 2020 21:20:30
User entered 'Day 49'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-30T19:23:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2f20881b-20bb-415d-b9be-b36982cc01e8' User entered 'No (N)'	System	01 Oct 2020 00:24:01
	System	01 Oct 2020 00:24:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-09-30T19:23:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '2f20881b-20bb-415d-b9be-b36982cc01e8' User entered '30 Sep 2020 19:23'	System	01 Oct 2020 00:24:01
	System	01 Oct 2020 00:24:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 00:23:52
User entered 'Day 50'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-01T18:03:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96b43640-c59b-4b64-aa44-52484bbd06a4' User entered 'No (N)'	System	01 Oct 2020 23:03:18
	System	01 Oct 2020 23:03:18

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-01T18:03:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '96b43640-c59b-4b64-aa44-52484bbd06a4' User entered '01 Oct 2020 18:03'	System	01 Oct 2020 23:03:18
	System	01 Oct 2020 23:03:18

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 00:23:52
User entered 'Day 51'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T11:53:30', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5fc4f7ea-de89-491d-98a2-1bbed41017ca' User entered 'No (N)'	System	03 Oct 2020 16:53:36
	System	03 Oct 2020 16:53:36

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T11:53:32', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '5fc4f7ea-de89-491d-98a2-1bbed41017ca' User entered '03 Oct 2020 11:53'	System	03 Oct 2020 16:53:36
	System	03 Oct 2020 16:53:36

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	01 Oct 2020 23:03:12
User entered 'Day 52'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T19:17:56', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bfb258c-8c1e-4bd1-9479-28e342a78a0a' User entered 'No (N)'	System	04 Oct 2020 00:18:03
	System	04 Oct 2020 00:18:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-03T19:17:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3bfb258c-8c1e-4bd1-9479-28e342a78a0a' User entered '03 Oct 2020 19:17'	System	04 Oct 2020 00:18:03
	System	04 Oct 2020 00:18:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	03 Oct 2020 16:53:29
User entered 'Day 53'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-04T15:19:49', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '297006b8-735f-4bae-8ac8-80fd6b4b3992'	System	04 Oct 2020 20:19:55
User entered 'No (N)'	System	04 Oct 2020 20:19:55

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-04T15:19:52', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '297006b8-735f-4bae-8ac8-80fd6b4b3992'	System	04 Oct 2020 20:19:55
User entered '04 Oct 2020 15:19'	System	04 Oct 2020 20:19:55

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Oct 2020 00:17:57
User entered 'Day 54'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	04 Oct 2020 20:19:49
User entered 'Day 55'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-06T23:09:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '996f036f-53c8-4ad3-921e-293926f1dbec' User entered 'No (N)'	System	07 Oct 2020 04:09:24
	System	07 Oct 2020 04:09:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-06T23:09:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '996f036f-53c8-4ad3-921e-293926f1dbec' User entered '06 Oct 2020 23:09'	System	07 Oct 2020 04:09:24
	System	07 Oct 2020 04:09:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Oct 2020 04:09:19
User entered 'Day 56'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	07 Oct 2020 04:09:19
User entered 'Day 57'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:44:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 04:09:19

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '20 Aug 2020'	Cindy Lubbers (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	20 Aug 2020 15:22:59

US3532020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	20 Aug 2020 15:22:59

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 07:49:41
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Unable to reach subject until this date' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:24:35
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 23:23:23
User entered '31 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 23:24:44

US3532020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	03 Sep 2020 23:24:44

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '3 Sep 2020'	Cindy Lubbers (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 23:27:36

US3532020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	03 Sep 2020 23:27:36

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:57:00
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirm' (Site from System).	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:26:37
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	18 Sep 2020 19:25:54
User entered '18 Sep 2020'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'VISIT2'	System	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User accepted default value 'Pre-Dose (PREDOSE)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '18 Sep 2020'	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '13:57'	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '18 Sep 2020 13:57'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '97' F	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Oral (Oral)'	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '69'	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'bpm'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '16'	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'breaths/min'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '139'	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'mmHg'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '88'	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'mmHg'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User accepted default value 'Post-Dose (POSTDOSE)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Per CDM: Please clarify why post dose vital signs were not assessed since this required per protocol.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 07:56:22
Query 'Per CDM: Please clarify why post dose vital signs were not assessed since this required per protocol.' answered with 'Subject did not get the dose.' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:28:11
User opened query 'Per CDM: Please clarify why post dose vital signs were not assessed since this required per protocol.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:43:25
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:26:51

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '18 Sep 2020'	Etza Peters (b) (4)	18 Sep 2020 19:26:51

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Per CDM: Please complete dosing discontinuation page under end of study folder.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 05:55:47
Query 'Per CDM: Please complete dosing discontinuation page under end of study folder.' answered with 'done' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:55:44
User opened query 'Per CDM: Please complete dosing discontinuation page under end of study folder.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:59:53
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

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)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'This dose was held and dosage withdrawn due to adverse #2. The subject will remain in study but no 2nd dosage.' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Nov 2020 17:03:10
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '18 Sep 2020'	Etza Peters (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '15:00'	Etza Peters (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '18 Sep 2020 15:00'	System	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:44:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	(b) (4)	18 Sep 2020 19:28:08
Query 'Samples were not collected, however Collection Date is provided. Please correct.' answered by data change (Site from System).	System	18 Sep 2020 19:28:08
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 19:28:08
User opened query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	(b) (4)	18 Sep 2020 19:27:52
User entered '18 Sep 2020'	System	18 Sep 2020 19:27:52
	Etza Peters (b) (4)	18 Sep 2020 19:27:52
	(b) (4)	

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered empty.	System	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:28:16

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '1'	System	18 Sep 2020 19:28:16

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered '26 Sep 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	06 Oct 2020 22:29:13
User entered '25 Sep 2020'	Cindy Lubbers (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered empty.	Cindy Lubbers (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:51:42
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	26 Sep 2020 14:39:43

US3532020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	26 Sep 2020 14:39:43

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 13:56:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:56:24
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:56:07
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Oct 2020 13:56:07
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:56:07
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:55:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 13:55:13
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Oct 2020 13:55:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:55:13
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:29:29
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:29
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:06

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '5 Sep 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:57:33
User entered '14 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:56:24
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:56:07
User entered '26 Sep 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:55:13
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:29
User entered '12 Oct 2020'	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:06

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 13:56:24
User entered empty; reason for change Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:06
	(b) (4)	

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:06

US3532020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Oct 2020 13:55:33

US3532020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	14 Oct 2020 13:55:33

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '14 Oct 2020'	Cindy Lubbers (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Oct 2020 13:58:36

US3532020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'I'	System	14 Oct 2020 13:58:36

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '19 Oct 2020'	Cindy Lubbers (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'VISIT3'	System	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 16:34:49
User entered '19 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	23 Oct 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 16:33:01
User entered empty.	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01
	(b) (4)	

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '12:38'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '19 Oct 2020 12:38'	System	23 Oct 2020 16:34:49
User entered empty.	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '98.3' F	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '73'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'bpm'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '18'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'breaths/min'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '142'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'mmHg'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '92'	Cindy Lubbers (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered 'mmHg'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30

US3532020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'No (N)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:34:54

US3532020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered empty.	Cindy Lubbers (b) (4)	23 Oct 2020 16:34:54

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '19 Oct 2020'	Cindy Lubbers (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered '12:47'	Cindy Lubbers (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '19 Oct 2020 12:47'	System	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:02:25
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 16:35:19

US3532020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:29:30
User entered '1'	System	23 Oct 2020 16:35:19

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 64'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-13T00:01:40', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9befbd55-22a3-49f3-9fa6-016374122e3e' User entered 'No (N)'	System	13 Oct 2020 04:02:02
	System	13 Oct 2020 04:02:02

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-13T00:01:49', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9befbd55-22a3-49f3-9fa6-016374122e3e'	System	13 Oct 2020 04:02:02
User entered 'No (N)'	System	13 Oct 2020 04:02:02

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-13T00:01:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9befbd55-22a3-49f3-9fa6-016374122e3e' User entered '13 Oct 2020 00:01:59'	System	13 Oct 2020 04:02:02
	System	13 Oct 2020 04:02:02

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 71'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-20T19:46:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '97603fd4-bf05-42c8-b2b6-e0c92b05e585'	System	20 Oct 2020 23:47:12
User entered 'No (N)'	System	20 Oct 2020 23:47:12

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-20T19:47:04', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '97603fd4-bf05-42c8-b2b6-e0c92b05e585'	System	20 Oct 2020 23:47:12
User entered 'No (N)'	System	20 Oct 2020 23:47:12

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-20T19:47:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '97603fd4-bf05-42c8-b2b6-e0c92b05e585' User entered '20 Oct 2020 19:47:08'	System	20 Oct 2020 23:47:12
	System	20 Oct 2020 23:47:12

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 78'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-27T01:13:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57ca8504-3be8-4185-ba98-986b57506c71' User entered 'No (N)'	System	27 Oct 2020 05:13:17
	System	27 Oct 2020 05:13:17

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-27T01:13:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57ca8504-3be8-4185-ba98-986b57506c71'	System	27 Oct 2020 05:13:17
User entered 'No (N)'	System	27 Oct 2020 05:13:17

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-10-27T01:13:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57ca8504-3be8-4185-ba98-986b57506c71' User entered '27 Oct 2020 01:13:15'	System	27 Oct 2020 05:13:17
	System	27 Oct 2020 05:13:17

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 92'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:57:27
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered 'Day 99'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-17T01:03:07', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'df87f6aa-b672-4cb8-8b14-cededc394ba8'	System	17 Nov 2020 06:03:24
User entered 'No (N)'	System	17 Nov 2020 06:03:24

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-17T01:03:13', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'df87f6aa-b672-4cb8-8b14-cededc394ba8'	System	17 Nov 2020 06:03:24
User entered 'No (N)'	System	17 Nov 2020 06:03:24

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-17T01:03:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'df87f6aa-b672-4cb8-8b14-cededc394ba8' User entered '17 Nov 2020 01:03:18'	System	17 Nov 2020 06:03:24
	System	17 Nov 2020 06:03:24

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:04:55

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:21:26
Data entry locked.	System	13 Aug 2020 17:04:55
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:04:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-25T17:34:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57a2b10d-c183-429c-a8a0-c34438eaf4a9' User entered 'No (N)'	System	25 Nov 2020 22:34:55
	System	25 Nov 2020 22:34:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-25T17:34:49', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57a2b10d-c183-429c-a8a0-c34438eaf4a9' User entered 'No (N)'	System	25 Nov 2020 22:34:55
	System	25 Nov 2020 22:34:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-25T17:34:53', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57a2b10d-c183-429c-a8a0-c34438eaf4a9' User entered '25 Nov 2020 17:34:53'	System	25 Nov 2020 22:34:55
	System	25 Nov 2020 22:34:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-30T17:26:12', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ca26f58-6e0e-4276-a21e-bf5907c6401e' User entered 'No (N)'	System	30 Nov 2020 22:26:21

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-30T17:26:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ca26f58-6e0e-4276-a21e-bf5907c6401e' User entered 'No (N)'	System	30 Nov 2020 22:26:21

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-11-30T17:26:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9ca26f58-6e0e-4276-a21e-bf5907c6401e' User entered '30 Nov 2020 17:26:19'	System	30 Nov 2020 22:26:21
	System	30 Nov 2020 22:26:21

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-05T15:52:46', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6d921c64-2ff8-49b7-9114-358a1c73bea8'	System	05 Dec 2020 20:52:55
User entered 'No (N)'	System	05 Dec 2020 20:52:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-05T15:52:49', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6d921c64-2ff8-49b7-9114-358a1c73bea8'	System	05 Dec 2020 20:52:55
User entered 'No (N)'	System	05 Dec 2020 20:52:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-05T15:52:52', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '6d921c64-2ff8-49b7-9114-358a1c73bea8' User entered '05 Dec 2020 15:52:52'	System	05 Dec 2020 20:52:55
	System	05 Dec 2020 20:52:55

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-13T16:36:14', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f6c7e359-1482-465e-844b-eadf06dbdf6b' User entered 'No (N)'	System	13 Dec 2020 21:37:06
	System	13 Dec 2020 21:37:06

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-13T16:36:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f6c7e359-1482-465e-844b-eadf06dbdf6b'	System	13 Dec 2020 21:37:06
User entered 'Yes (Y)'	System	13 Dec 2020 21:37:06

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-13T16:36:51', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f6c7e359-1482-465e-844b-eadf06dbdf6b'	System	13 Dec 2020 21:37:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 21:37:06

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-13T16:36:57', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'f6c7e359-1482-465e-844b-eadf06dbdf6b' User entered '13 Dec 2020 16:36:57'	System	13 Dec 2020 21:37:06
	System	13 Dec 2020 21:37:06

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-19T09:34:42', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3b1533d2-1bbe-409a-8375-5bd99636d317'	System	19 Dec 2020 14:34:54
User entered 'No (N)'	System	19 Dec 2020 14:34:54

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-19T09:34:48', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3b1533d2-1bbe-409a-8375-5bd99636d317' User entered 'No (N)'	System	19 Dec 2020 14:34:54

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-19T09:34:52', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3b1533d2-1bbe-409a-8375-5bd99636d317' User entered '19 Dec 2020 09:34:52'	System	19 Dec 2020 14:34:54
	System	19 Dec 2020 14:34:54

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-26T11:00:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0184aa77-e623-432a-b291-dd081304c80f' User entered 'No (N)'	System	26 Dec 2020 16:00:22
	System	26 Dec 2020 16:00:22

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-26T11:00:13', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0184aa77-e623-432a-b291-dd081304c80f' User entered 'No (N)'	System	26 Dec 2020 16:00:22
	System	26 Dec 2020 16:00:22

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2020-12-26T11:00:19', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '0184aa77-e623-432a-b291-dd081304c80f' User entered '26 Dec 2020 11:00:19'	System	26 Dec 2020 16:00:22
	System	26 Dec 2020 16:00:22

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-02T08:29:34', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e3d34d2d-4433-4a57-bb9b-dbf7263fc88a'	System	02 Jan 2021 13:29:48
User entered 'No (N)'	System	02 Jan 2021 13:29:48

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-02T08:29:39', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e3d34d2d-4433-4a57-bb9b-dbf7263fc88a' User entered 'No (N)'	System	02 Jan 2021 13:29:48
	System	02 Jan 2021 13:29:48

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-02T08:29:43', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e3d34d2d-4433-4a57-bb9b-dbf7263fc88a' User entered '02 Jan 2021 08:29:43'	System	02 Jan 2021 13:29:48
	System	02 Jan 2021 13:29:48

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-09T09:38:29', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3609f4fd-622a-43ab-bf0c-a03aeae5ddde' User entered 'No (N)'	System	09 Jan 2021 14:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-09T09:38:33', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3609f4fd-622a-43ab-bf0c-a03aeae5ddde' User entered 'No (N)'	System	09 Jan 2021 14:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-09T09:38:36', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3609f4fd-622a-43ab-bf0c-a03aeae5ddde' User entered '09 Jan 2021 09:38:36'	System	09 Jan 2021 14:38:38
	System	09 Jan 2021 14:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-16T09:44:17', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3e798a4c-fcdd-40d3-aef1-66a5c6e9c131' User entered 'No (N)'	System	16 Jan 2021 14:44:28
	System	16 Jan 2021 14:44:28

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-16T09:44:22', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3e798a4c-fcdd-40d3-aef1-66a5c6e9c131' User entered 'No (N)'	System	16 Jan 2021 14:44:28

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-16T09:44:26', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '3e798a4c-fcdd-40d3-aef1-66a5c6e9c131' User entered '16 Jan 2021 09:44:26'	System	16 Jan 2021 14:44:28
	System	16 Jan 2021 14:44:28

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-23T03:48:51', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1e13321d-5994-45c4-aeff-1c67006b936a' User entered 'No (N)'	System	23 Jan 2021 08:49:05

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-23T03:48:54', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1e13321d-5994-45c4-aeff-1c67006b936a' User entered 'No (N)'	System	23 Jan 2021 08:49:05

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-23T03:48:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '1e13321d-5994-45c4-aeff-1c67006b936a' User entered '23 Jan 2021 03:48:59'	System	23 Jan 2021 08:49:05
	System	23 Jan 2021 08:49:05

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-30T11:51:20', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '40358420-4acd-4a44-8d14-9441e282e60b'	System	30 Jan 2021 16:51:29
User entered 'No (N)'	System	30 Jan 2021 16:51:29

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-30T11:51:23', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '40358420-4acd-4a44-8d14-9441e282e60b'	System	30 Jan 2021 16:51:29
User entered 'No (N)'	System	30 Jan 2021 16:51:29

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-01-30T11:51:27', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '40358420-4acd-4a44-8d14-9441e282e60b' User entered '30 Jan 2021 11:51:27'	System	30 Jan 2021 16:51:29
	System	30 Jan 2021 16:51:29

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-06T14:16:32', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e33fb68f-7e7a-4c61-a9bd-65564666f2fd' User entered 'No (N)'	System	06 Feb 2021 19:16:42

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-06T14:16:35', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e33fb68f-7e7a-4c61-a9bd-65564666f2fd' User entered 'No (N)'	System	06 Feb 2021 19:16:42

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-06T14:16:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'e33fb68f-7e7a-4c61-a9bd-65564666f2fd' User entered '06 Feb 2021 14:16:38'	System	06 Feb 2021 19:16:42
	System	06 Feb 2021 19:16:42

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-13T13:54:38', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '824f3cca-eca5-4e66-b3d3-81a46218c9e5' User entered 'No (N)'	System	13 Feb 2021 18:54:47
	System	13 Feb 2021 18:54:47

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-13T13:54:41', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '824f3cca-eca5-4e66-b3d3-81a46218c9e5'	System	13 Feb 2021 18:54:47
User entered 'No (N)'	System	13 Feb 2021 18:54:47

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-13T13:54:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '824f3cca-eca5-4e66-b3d3-81a46218c9e5' User entered '13 Feb 2021 13:54:45'	System	13 Feb 2021 18:54:47
	System	13 Feb 2021 18:54:47

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-20T21:47:31', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '7e9c07fb-a0eb-49f8-97a0-7f61e4d757e7'	System	21 Feb 2021 02:47:49
User entered 'No (N)'	System	21 Feb 2021 02:47:49

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-20T21:47:37', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '7e9c07fb-a0eb-49f8-97a0-7f61e4d757e7'	System	21 Feb 2021 02:47:49
User entered 'No (N)'	System	21 Feb 2021 02:47:49

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-20T21:47:45', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '7e9c07fb-a0eb-49f8-97a0-7f61e4d757e7' User entered '20 Feb 2021 21:47:45'	System	21 Feb 2021 02:47:49

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:03:54-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'dd7f4b36-3c3a-4417-bf60-4c9f508c0d64'	System	28 Feb 2021 03:07:58
User entered 'No (N)'	System	28 Feb 2021 03:07:58

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:04:05-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'dd7f4b36-3c3a-4417-bf60-4c9f508c0d64'	System	28 Feb 2021 03:07:58
User entered 'No (N)'	System	28 Feb 2021 03:07:58

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:04:09-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'dd7f4b36-3c3a-4417-bf60-4c9f508c0d64'	System	28 Feb 2021 03:07:58
User entered '28 Feb 2021 03:04:09'	System	28 Feb 2021 03:07:58

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-06T17:38:12-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9984ad32-190d-4906-adee-21c2c8943fa3'	System	06 Mar 2021 22:38:38
User entered 'No (N)'	System	06 Mar 2021 22:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-06T17:38:22-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9984ad32-190d-4906-adee-21c2c8943fa3'	System	06 Mar 2021 22:38:38
User entered 'No (N)'	System	06 Mar 2021 22:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-06T17:38:33-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9984ad32-190d-4906-adee-21c2c8943fa3' User entered '06 Mar 2021 17:38:33'	System	06 Mar 2021 22:38:38
	System	06 Mar 2021 22:38:38

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-20T14:26:56-04:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '86c37e82-915b-49b5-9cd0-50c290788450'	System	20 Mar 2021 18:27:08
User entered 'No (N)'	System	20 Mar 2021 18:27:08

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Have you been exposed to someone with 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 (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-20T14:27:01-04:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '86c37e82-915b-49b5-9cd0-50c290788450'	System	20 Mar 2021 18:27:08
User entered 'No (N)'	System	20 Mar 2021 18:27:08

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-03-20T14:27:05-04:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '86c37e82-915b-49b5-9cd0-50c290788450'	System	20 Mar 2021 18:27:08
User entered '20 Mar 2021 14:27:05'	System	20 Mar 2021 18:27:08

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:57:27

US3532020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:44:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:04:45-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '921ef1db-36a3-4050-ab5a-7d716e2841bb'	System	28 Feb 2021 03:09:06
User entered 'Yes (Y)'	System	28 Feb 2021 03:09:06

US3532020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:44:42

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:05:01-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '921ef1db-36a3-4050-ab5a-7d716e2841bb' User entered 'No (N)'	System	28 Feb 2021 03:09:06
	System	28 Feb 2021 03:09:06

US3532020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:44:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:43:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3CB4DC3-F4B5-4B2E-BB79-7335174CF345)', Time: '2021-02-27T22:05:19-05:00', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '921ef1db-36a3-4050-ab5a-7d716e2841bb' User entered '28 Feb 2021 03:05:19'	System	28 Feb 2021 03:09:06
	System	28 Feb 2021 03:09:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:32:37
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:32:37
User entered '10 Nov 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:32:37
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:32:37
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:32:37
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Dec 2020 15:51:57

US3532020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:05:02
User entered 'I'	System	14 Dec 2020 15:51:57

US3532020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Dec 2020 15:52:10

US3532020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '14 Dec 2020'	Cindy Lubbers (b) (4)	14 Dec 2020 15:52:10

US3532020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	14 Dec 2020 15:52:10

US3532020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	14 Dec 2020 15:52:10

US3532020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Dec 2020 15:52:32

US3532020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'I'	System	14 Dec 2020 15:52:32

US3532020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	15 Jan 2021 19:40:59

US3532020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '15 Jan 2021'	Cindy Lubbers (b) (4)	15 Jan 2021 19:40:59

US3532020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	15 Jan 2021 19:40:59

US3532020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	15 Jan 2021 19:40:59

US3532020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	15 Jan 2021 19:41:22

US3532020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered '1'	System	15 Jan 2021 19:41:22

US3532020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	15 Feb 2021 19:36:07

US3532020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '9 Feb 2021'	Cindy Lubbers (b) (4)	15 Feb 2021 19:36:07

US3532020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	15 Feb 2021 19:36:07

US3532020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	15 Feb 2021 19:36:07

US3532020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	15 Feb 2021 19:36:17

US3532020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'I'	System	15 Feb 2021 19:36:17

US3532020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 19:52:53

US3532020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '29 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 19:52:53

US3532020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	29 Mar 2021 19:52:53

US3532020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'VISIT4'	System	29 Mar 2021 19:52:53

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '29 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '11:58'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered '29 Mar 2021 11:58'	System	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '98' F	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (Oral)'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '72'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'bpm'	System	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '16'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'breaths/min'	System	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '114'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'mmHg'	System	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '72'	Etza Peters (b) (4)	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'mmHg'	System	29 Mar 2021 19:54:23

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11

US3532020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11

US3532020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 19:54:28

US3532020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 19:54:28

US3532020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 19:54:45

US3532020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '29 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 19:54:45

US3532020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '11:58'	Etza Peters (b) (4)	29 Mar 2021 19:54:45

US3532020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered '29 Mar 2021 11:58'	System	29 Mar 2021 19:54:45

US3532020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 19:54:52

US3532020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:11
User entered 'I'	System	29 Mar 2021 19:54:52

US3532020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:35:14
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Apr 2021 19:47:45
	(b) (4)	

US3532020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:35:14
	(b) (4)	
User entered '14 Apr 2021'	Cindy Lubbers (b) (4)	14 Apr 2021 19:47:45
	(b) (4)	

US3532020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:35:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	14 Apr 2021 19:47:45

US3532020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:35:14
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	14 Apr 2021 19:47:45
	(b) (4)	

US3532020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:35:14
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	14 Apr 2021 19:47:49
	(b) (4)	

US3532020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:47:49

US3532020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:38:55

US3532020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:38:55

US3532020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[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 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:38:55

US3532020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 18:38:55

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:49:48

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:49:48

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Placebo (Placebo)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Placebo (Placebo)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Placebo (Placebo)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1'	System	02 Feb 2021 18:39:16

US3532020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:44:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'I'	System	02 Feb 2021 18:39:16

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered empty.	System	02 Feb 2021 18:43:39
DataPoint set to visible.	System	02 Feb 2021 18:39:16

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered empty.	System	02 Feb 2021 18:43:39
DataPoint set to visible.	System	02 Feb 2021 18:39:16

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '11:45'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '2 Feb 2021 11:45'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '98.4' F	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (Oral)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '81'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'bpm'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '18'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'breaths/min'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '135'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '94'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered missing code ND - Not Done.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered empty.	System	02 Feb 2021 18:43:39
DataPoint set to visible.	System	02 Feb 2021 18:39:16

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '13:10'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '2 Feb 2021 13:10'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '99.1' F	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '82'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'bpm'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '18'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'breaths/min'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '142'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '86'	Cindy Lubbers (b) (4)	02 Feb 2021 18:43:39

US3532020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	02 Feb 2021 18:43:39

US3532020

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:41:02

US3532020

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:41:02

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mRNA-1273'	System	02 Feb 2021 18:40:30
DataPoint set to visible.	System	02 Feb 2021 18:39:16

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '12:35'	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '2 Feb 2021 12:35'	System	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Right Arm (RIGHT ARM)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'ONCE'	System	02 Feb 2021 18:40:30

US3532020

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

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 18:40:30

US3532020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:39

US3532020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:39

US3532020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '12:13'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:39

US3532020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '2 Feb 2021 12:13'	System	02 Feb 2021 18:39:39

US3532020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:55

US3532020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '2 Feb 2021'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:55

US3532020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '12:08'	Cindy Lubbers (b) (4)	02 Feb 2021 18:39:55

US3532020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '2 Feb 2021 12:08'	System	02 Feb 2021 18:39:55

US3532020

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

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 18:40:00

US3532020

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

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1'	System	02 Feb 2021 18:40:00

US3532020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Feb 2021 21:28:51

US3532020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '9 Feb 2021'	Cindy Lubbers (b) (4)	09 Feb 2021 21:28:51

US3532020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Feb 2021 21:28:51

US3532020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	09 Feb 2021 21:28:51

US3532020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Feb 2021 21:28:54

US3532020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'I'	System	09 Feb 2021 21:28:54

US3532020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1'	System	09 Feb 2021 21:28:54
DataPoint set to visible.	System	09 Feb 2021 21:28:54

US3532020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:28:22

US3532020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '1 Mar 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:28:22

US3532020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[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 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:28:22

US3532020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'OLD29'	System	01 Mar 2021 20:28:22

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '1 Mar 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '12:10'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1 Mar 2021 12:10'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '97.3' F	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '77'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'bpm'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '18'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'breaths/min'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '147'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '90'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '1 Mar 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '13:30'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1 Mar 2021 13:30'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '98.3' F	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (Oral)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '80'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'bpm'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '18'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'breaths/min'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '150'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '90'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mmHg'	System	01 Mar 2021 20:34:49

US3532020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:57

US3532020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '1 Mar 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:34:57

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'mRNA-1273'	System	01 Mar 2021 20:35:26
DataPoint set to visible.	System	09 Feb 2021 21:28:54

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '1 Mar 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '12:57'	Cindy Lubbers (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered '1 Mar 2021 12:57'	System	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:37:30
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Last visit subject requested right arm last visit but left arm this visit.' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:38:53
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	01 Mar 2021 20:35:26
User entered 'Left Arm (LEFT ARM)'	Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'ONCE'	System	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 20:35:26

US3532020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:39:03

US3532020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'I'	System	01 Mar 2021 20:39:03

US3532020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	10 Mar 2021 21:34:36

US3532020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '10 Mar 2021'	Cindy Lubbers (b) (4)	10 Mar 2021 21:34:36

US3532020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	10 Mar 2021 21:34:36

US3532020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	10 Mar 2021 21:34:36

US3532020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	10 Mar 2021 21:34:40

US3532020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:30
User entered 'I'	System	10 Mar 2021 21:34:40

US3532020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 19:55:04
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '29 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 19:55:04
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	29 Mar 2021 19:55:04
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 19:55:04

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '29 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '11:50'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 11:50'	System	29 Mar 2021 20:03:45

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '98' F	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (Oral)'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '72'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:03:45

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '16'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:03:45

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '114'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:03:45

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '72'	Etza Peters (b) (4)	29 Mar 2021 20:03:45
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:03:45

US3532020

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 20:03:56
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:03:56
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 20:04:55
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:06:29
User entered '29 Mar 2021' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 20:06:29
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:04:55
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:04:55
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '11:58'	Etza Peters (b) (4)	29 Mar 2021 20:04:55
	(b) (4)	

US3532020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 11:58'	System	29 Mar 2021 20:06:29
User entered empty.	System	29 Mar 2021 20:04:55

US3532020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:44:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:18
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:36:33

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:30:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:30:41
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 18:39:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 18:39:56
	(b) (4)	
Data point term sent to Coder System	System	09 Sep 2020 18:39:33
User entered 'Soreness at injection site'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '13 Aug 2020'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 18:41:44
User entered '16:33' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:41:44
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 18:38:40
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User entered '13 Aug 2020 16:33'	System	09 Sep 2020 18:41:44
User entered empty.	System	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:13:58
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '16 Aug 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:13:58
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 05:58:50
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Etza Peters (b) (4)	18 Sep 2020 20:14:04
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 20:13:58
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User entered empty.	System	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:43:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 18:43:18
User entered 'Related (RELATED)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:43:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:38:40
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:43:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 18:43:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:43:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:38:40
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:43:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 18:43:18
User entered 'None (NONE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:43:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:38:40
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	09 Sep 2020 18:43:18
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	09 Sep 2020 18:38:40
User entered 'I'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:43:18
	(b) (4)	
User entered '1'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Etza Peters (b) (4)	18 Sep 2020 20:13:58
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User entered '0'	System	09 Sep 2020 18:38:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17
User entered '0'	System	09 Sep 2020 18:38:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Peripheral nerve injuries, PT: Ulnar nerve injury, LLT: Injury to ulnar nerve - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:01:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:01:53
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 20:16:32
User entered 'Ulnar Nerve Irritation'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '16 Aug 2020'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User entered empty.	System	18 Sep 2020 20:16:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:07:01
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:07:01
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User entered empty.	System	18 Sep 2020 20:16:02

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Related (RELATED)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
User closed query 'Per DM CLR-Requery: Response noted. However, note: Action taken with investigational product=Investigational Product withdrawn; but Dosing discontinuation ecrf does not contain this information. Either update this field or update dosing discontinuation ecrf. Seek CRA assistance as necessary . Else, provide further clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:58:27
Query 'Per DM CLR-Requery: Response noted. However, note: Action taken with investigational product=Investigational Product withdrawn; but Dosing discontinuation ecrf does not contain this information. Either update this field or update dosing discontinuation ecrf. Seek CRA assistance as necessary . Else, provide further clarification.' answered with 'clarification note under Exposure in Day 2' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	13 Nov 2020 17:04:33
User opened query 'Per DM CLR-Requery: Response noted. However, note: Action taken with investigational product=Investigational Product withdrawn; but Dosing discontinuation ecrf does not contain this information. Either update this field or update dosing discontinuation ecrf. Seek CRA assistance as necessary . Else, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:21:32
User closed query 'Per DM CLR - Requery: Response noted, however, the response to this field remains the same even if the noted reason for withdrawing from investigational product is different. Please update as appropriate ensuring the noted reason is also reflected in the Dosing Discontinuation eCRF page. Reconcile, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR - Requery: Response noted, however, the response to this field remains the same even if the noted reason for withdrawing from investigational product is different. Please update as appropriate ensuring the noted reason is also reflected in the Dosing Discontinuation eCRF page. Reconcile, otherwise provide clarification.' answered with 'Appropriate. Treatment discontinuation form in chart under Misc tab. Product withdrawn due to AE #2' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	11 Nov 2020 16:10:21
User opened query 'Per DM CLR - Requery: Response noted, however, the response to this field remains the same even if the noted reason for withdrawing from investigational product is different. Please update as appropriate ensuring the noted reason is also reflected in the Dosing Discontinuation eCRF page. Reconcile, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:22:26
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:22:26
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'did not meet inclusion criteria for product but is continuing in study' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 21:58:41
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:17:06
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 20:16:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 20:16:02
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:16:48
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cindy Lubbers (b) (4)	19 Oct 2020 19:07:01
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User entered '0'	System	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20
User entered '1'	System	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:44:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:00:20

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 20:45:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 20:45:56
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 20:45:15
User entered 'Exacerbation of osteoarthritis'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '25 Feb 2021'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'None (NONE)'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered 'I'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:05:51
User entered 'Subject had exacerbation of osteoarthritis in back/neck area. Went to orthopedist who will do an MRI on Wednesday and most likely give a steroid injection. Subject will make us aware of when this happens'	(b) (4) Cindy Lubbers (b) (4)	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:44:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 20:45:06

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal foot infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Mar 2021 10:06:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:06:27
Data point term sent to Coder	System	29 Mar 2021 20:09:03
User entered 'Worsening Toe Fungal Infection'	Etza Peters (b) (4) (b) (4)	29 Mar 2021 20:08:47

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '24 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:08:47

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:08:47

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 20:08:58
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 20:08:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:47
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 21:19:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 21:19:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 21:19:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:47
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 21:19:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 21:19:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 21:19:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:47
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 20:08:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 20:08:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:08:47
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 20:08:47
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 20:08:58

US3532020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:44:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 20:08:47

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:18
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 06:34:02
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Completed' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	07 Apr 2021 13:42:33
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:08:30
User closed query 'Per DM CLR: Per Diary Dose 1 Day 21 to 55, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:29:49

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 21 to 55, Cindy Lubbers (b) (4) Pain at Injection Site = Repeated use of (b) (4) over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject was taking Aleve originally and then alternated with Gabapentin and Aleve. Added Aleve to conmeds' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 1 (b) (4), (b) (6) Day 21 to 55, Pain at Injection Site = Repeated use of (b) (4) over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4) Laila Hussaini (b) (4) (b) (4)	12 Feb 2021 20:53:00 09 Feb 2021 09:55:27 13 Aug 2020 19:20:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:38:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:38:12
Data point term sent to Coder	System	13 Aug 2020 19:37:32
Data point term sent to Coder	System	13 Aug 2020 19:25:02
User entered 'levothyroxine'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'hypothyroidism' reason for change:	Laila Hussaini (b) (4)	13 Aug 2020 19:37:06
Data Entry Error	(b) (4)	
User entered 'Medical hx # 1'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '88'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	02 Nov 2020 20:03:13
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.	(b) (4), (b) (6)	28 Sep 2020 10:46:33
' (Site from DM).		
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.	Cindy Lubbers (b) (4)	26 Sep 2020 19:43:02
' answered with 'done' (Site from DM).	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 19:42:50
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.	(b) (4), (b) (6)	22 Sep 2020 06:52:29
' (Site from DM).		
User entered 'mg (mg)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:50:24
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:03:23
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:03:13
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:54:22
User entered 'mcg' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:42:50
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:24:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 22:48:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:24:24
User entered 'un UNK 2003'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:24:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:24:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:24:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Sep 2020 13:13:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 13:13:40
Data point term sent to Coder	System	26 Sep 2020 19:44:26
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:44:12
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 06:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 06:59:47
Data point term sent to Coder	System	07 Sep 2020 18:27:57
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	07 Sep 2020 18:27:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST, PRODUCTSYNONYM: LUMIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:47:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:47:19
Data point term sent to Coder	System	13 Aug 2020 19:38:35
Data point term sent to Coder	System	13 Aug 2020 19:27:10
User entered 'Lumigan 0.01 %'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please update the indication to reflect the location of GLAUCOMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 10:47:43
Query 'Per DM CLR: Please update the indication to reflect the location of GLAUCOMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:44:24
User entered 'GLAUCOMA both eyes' reason for change: New Information	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:44:12
User opened query 'Per DM CLR: Please update the indication to reflect the location of GLAUCOMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:52:48
User entered 'Glaucoma' reason for change: New Information	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:37:41
User entered 'medical hx # 2'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Drop'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 02:51:44
Query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	07 Sep 2020 18:29:37
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	07 Sep 2020 18:27:43
User opened query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 03:30:23
User entered 'Other (OTHER)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	07 Sep 2020 18:27:43
	(b) (4)	
User entered 'Ophthalmic'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 22:48:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:27:08
User entered 'un UNK 2018'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:27:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:29:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:29:09
Data point term sent to Coder	System	13 Aug 2020 19:28:13
User entered 'Magnesium'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'general health'	(b) (4) Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '400'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (ORAL)'	(b) (4) Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:22:16
User entered 'un UNK 2019' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:22:16
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:27:55
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per MM: Please clarify the reported CM term.' (Site from DM).	(b) (4)	
Query 'Per MM: Please clarify the reported CM term.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:53:28
User opened query 'Per MM: Please clarify the reported CM term.' (Site from DM).	Cindy Lubbers (b) (4)	07 Sep 2020 18:32:08
	(b) (4)	
	(b) (4), (b) (6)	07 Sep 2020 15:25:06
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Aug 2020 20:25:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Aug 2020 20:25:45
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 20:24:13
User closed query '	System	28 Aug 2020 20:23:58
DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Query '	Cindy Lubbers (b) (4)	28 Aug 2020 20:23:58
	(b) (4)	
DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' answered with 'DONE' (Site from System).		
User entered 'ALEVE' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:23:49
	(b) (4)	
User opened query '	Coder Import (b) (4)	14 Aug 2020 06:09:09
	(b) (4)	
DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Data point term sent to Coder	System	13 Aug 2020 19:38:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	13 Aug 2020 19:29:15
User entered 'Allere'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'osteoarthritis' reason for change: New Information	Laila Hussaini (b) (4)	13 Aug 2020 19:38:19
	(b) (4)	
User entered 'medical hx # 3'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 10:02:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:48:20
User entered '220' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:48:07
User entered '229' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 19:47:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:52:03
User entered '1-2'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:28:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:50:41
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:04:30
User entered 'mg (mg)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:04:23
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:54:52
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:23:49
User entered 'UN UNK 2013' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:23:49
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:28:53
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:28:53
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:40:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:40:09
Data point term sent to Coder Coding entries removed.	System Laila Hussaini (b) (4)	13 Aug 2020 19:39:36 13 Aug 2020 19:38:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:31:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:31:08
Data point term sent to Coder User entered 'Allegra'	System Laila Hussaini (b) (4)	13 Aug 2020 19:30:16 13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'seasonal allergies' reason for change:	Laila Hussaini (b) (4)	13 Aug 2020 19:38:44
Data Entry Error	(b) (4)	
User entered 'medical hx # 5'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '180'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:24:37
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:29:32
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:24:37
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:29:32
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:50:54
Query 'Per DM CLR: Please provide brand name if known. ' answered with 'not known' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:04:46
User opened query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:53:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:32:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:32:11
Data point term sent to Coder	System	13 Aug 2020 19:31:21
User entered 'multivitamin'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'general health'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:25:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 20:25:43
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:25:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:30:46
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:25:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 20:25:33
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:25:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:30:46
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 22:49:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:39:19
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:39:19
User entered 'un UNK 2019' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:39:19
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:30:46
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:30:46
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:33:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:33:12
Data point term sent to Coder	System	13 Aug 2020 19:32:23
User entered 'Calcium'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'General Health'	(b) (4) Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unk'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unk'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'occasionally'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:26:08
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:31:41
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:26:08
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:31:41
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:37:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:37:09
Data point term sent to Coder	System	13 Aug 2020 19:36:31
User entered 'Benadryl'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'seasonal allergies'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unk'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unk'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 19:36:29
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:36:13
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:36:29
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:36:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:36:32
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:36:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:36:13
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:36:13
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 00:53:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:53:10
Data point term sent to Coder	System	13 Aug 2020 19:42:40
User entered 'Voltaren Cream'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'osteoarthritis'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unk'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'UNK'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Topical (TOPICAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'I'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:26:41
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		28 Aug 2020 20:26:41
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		13 Aug 2020 19:42:06
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTS YNOM: SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:50:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:50:11
Data point term sent to Coder	System	22 Aug 2020 16:49:56
Coding entries removed.	Cindy Lubbers (b) (4)	22 Aug 2020 16:49:37
User entered 'simethicone' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:49:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:12:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:12:22
Data point term sent to Coder	System	13 Aug 2020 19:44:45
User entered 'Simeticone'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Gas'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '125'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '4x week'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 22:49:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:46:06
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:46:06
User entered 'un UNK 2005' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:46:06
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:44:45
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	(b) (4) Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:55:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:55:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:55:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:44:45
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:44:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:44:51
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:44:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:44:45
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:44:45
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 01:21:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:21:10
Data point term sent to Coder	System	13 Aug 2020 19:45:47
User entered 'Tums'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Gas'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '500' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:51:44
	(b) (4)	
User entered '100'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'other (OTHER)'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '4x week'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 22:49:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:45:42
User entered 'un UNK 2005'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:56:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:56:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:56:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:45:42
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:45:48
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:45:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:45:42
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:51:41
Data point term sent to Coder	System	18 Sep 2020 20:18:37
Data point term sent to Coder	System	18 Sep 2020 20:09:18
Data point term sent to Coder	System	18 Sep 2020 19:36:48
User entered 'Diclofenac'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 19:36:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:36:38
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 19:36:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 19:36:25
User entered empty.	System	18 Sep 2020 19:36:25
	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'ULNAr NERVE IRRITATION'	(b) (4)	
reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:18:14
User entered 'Ulna Nerve Irritation' reason for	(b) (4)	
change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:09:11
User entered 'Pain at injection site'	(b) (4)	
	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'unknown'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'unknown'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 19:41:44
User entered 'other (OTHER)'	(b) (4)	
	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:41:44
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	18 Sep 2020 19:36:25
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Topical (TOPICAL)'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'un Aug 2020'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:51:10
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:02:29
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:00:57
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:38:05
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:57
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 20:18:14
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:36:25
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User entered empty.	System	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User entered empty.	System	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:33
User entered empty.	System	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 22:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:55:43
Data point term sent to Coder	System	18 Sep 2020 20:19:38
Data point term sent to Coder	System	18 Sep 2020 20:12:21
Data point term sent to Coder	System	18 Sep 2020 19:43:04
User entered 'Gabapentin'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'ULNAR NERVE IRRITATION' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:18:38
User entered 'Ulna Nerve Irritation' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:12:06
User entered 'Pain at injection site'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '300'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'mg (mg)'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'as needed (PRN)'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 19:43:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:43:00
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 19:43:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 19:42:52
User entered empty.	System	18 Sep 2020 19:42:52
	Etza Peters (b) (4)	18 Sep 2020 19:42:52
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '16 Sep 2020'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	Etza Peters (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:49:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 21:55:02
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 21:54:53
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:38:12
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	04 Nov 2020 21:54:53
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	18 Sep 2020 19:42:52
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 20:18:38
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 19:42:52
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User entered empty.	System	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User entered empty.	System	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:01:42
User entered empty.	System	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, PRODUCT: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 02:31:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:31:39
Data point term sent to Coder	System	24 Nov 2020 17:16:02
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	24 Nov 2020 17:15:59
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'unknown to subject' (Site from System).	Laila Hussaini (b) (4) (b) (4)	24 Nov 2020 17:15:59
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 11:42:15
Data point term sent to Coder	System	02 Nov 2020 20:00:38
User entered 'knee injections'	Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:00:05

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'osteoarthritis'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'injection'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	02 Nov 2020 20:00:05

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'un Jun 2020'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:05
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 20:00:05

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 20:00:05

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 20:00:05

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 22:10:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:10:34
Data point term sent to Coder	System	04 Nov 2020 21:56:54
User entered 'gabbapentin'	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 21:56:36

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 10:25:09
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'Subject states she take this about twice a month when her osteoarthritis is bothering her at night - it helps her sleep. It is not a case of worsening osteoarthritis.' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	05 Feb 2021 15:15:57
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:44:46
User entered 'osteoarthritis'	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 21:56:36

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '300'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '15 Oct 2020'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	04 Nov 2020 21:56:36
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:56:36

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:56:36

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:56:36

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: STEROIDS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 08:54:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:54:19
Data point term sent to Coder	System	04 Nov 2020 22:02:02
User entered 'SPINAL STEROID INJECTIONS'	Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 22:02:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'osteoarthritis'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '1'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Other (OTHER)'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'injection'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	04 Nov 2020 22:02:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'un UNK 1988'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	04 Nov 2020 22:02:02
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:02:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:02:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:02:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:06:41
Data point term sent to Coder	System	10 Nov 2020 23:06:00
User entered 'FLU VACCINE'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 06:45:49
Query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	12 Jan 2021 14:31:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	12 Jan 2021 14:31:22
User opened query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:12:21
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 08:28:26
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' answered with 'updated' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	26 Jan 2021 14:49:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:44:01
User entered 'FLU PREVENTION'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'I'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'INJECTION'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'other (OTHER)'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'YEARLY'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '19 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '19 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User entered empty.	System	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User entered empty.	System	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:13
User entered empty.	System	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 20:53:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 20:53:52
Data point term sent to Coder User entered 'Aleve'	System Cindy Lubbers (b) (4)	12 Feb 2021 20:53:02 12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User closed query 'Per DM CLR: Please note that there is no AE condition recorded that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 05:42:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Per DM CLR: Please note that there is no AE condition recorded that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' answered with 'AE - corrected dates' (Site from DM).	(b) (4) Cindy Lubbers (b) (4)	31 Mar 2021 21:43:58
User opened query 'Per DM CLR: Please note that there is no AE condition recorded that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:21:01
User entered 'Pain at injection site'	Cindy Lubbers (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '220'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'mg (mg)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Oral (ORAL)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	(b) (4) Cindy Lubbers (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	31 Mar 2021 21:42:43
User entered '2 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	12 Feb 2021 20:52:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	31 Mar 2021 21:42:43
User entered '6 Oct 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	12 Feb 2021 20:52:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User entered empty.	System	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User entered empty.	System	12 Feb 2021 20:52:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:23
User entered empty.	System	12 Feb 2021 20:52:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 07:21:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 07:21:47
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:32:14
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' answered with 'complete' (Site from DM).	Cindy Lubbers (b) (4)	07 Apr 2021 13:37:59
Data point term sent to Coder Coding entries removed.	System	07 Apr 2021 13:37:56
Signature has been broken.	Cindy Lubbers (b) (4)	07 Apr 2021 13:37:53
User entered 'EPIDURAL STEROID INJECTION-Ascent (amniotic stem cells)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	07 Apr 2021 13:37:53
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:21:16
Data hard unlocked.	(b) (4), (b) (6)	06 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 11:21:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:26:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:26:16
Data point term sent to Coder	System	29 Mar 2021 21:10:27
User entered 'Epidural Steroid Injection'	Etza Peters (b) (4) (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 21:09:46
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	29 Mar 2021 21:09:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Mar 2021 21:09:38
	Etza Peters (b) (4)	29 Mar 2021 21:09:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User closed query 'Per DM CLR: Please review AE eCRF's AE #3 EXACERBATION OF OSTEOARTHRITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:32:33
Query 'Per DM CLR: Please review AE eCRF's AE #3 EXACERBATION OF OSTEOARTHRITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'Corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	06 Apr 2021 20:07:19
User opened query 'Per DM CLR: Please review AE eCRF's AE #3 EXACERBATION OF OSTEOARTHRITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:21:23
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 18:46:20
User entered 'Exacerbation of osteoarthritis'	Etza Peters (b) (4) (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User closed query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4)	
Query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:32:38
Signature has been broken.	Cindy Lubbers (b) (4)	06 Apr 2021 20:02:08
	(b) (4)	
User entered 'UNK' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	06 Apr 2021 20:02:01
	(b) (4)	
User opened query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:47:18
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unknown'	Etza Peters (b) (4)	29 Mar 2021 21:09:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'unknown'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'once (ONCE)'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'joint'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '11 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '11 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User entered empty.	System	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User entered empty.	System	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:40
User entered empty.	System	29 Mar 2021 21:09:38

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROIDS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 13:26:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:26:16
Data point term sent to Coder	System	29 Mar 2021 21:12:29
User entered 'Epidural Steroid Injection'	Etza Peters (b) (4) (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Exacerbation of osteoarthritis'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:23:03
User closed query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4)	
Query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:33:17
Signature has been broken.	Cindy Lubbers (b) (4)	06 Apr 2021 19:58:22
	(b) (4)	
User entered 'UNK' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	06 Apr 2021 19:58:12
	(b) (4)	
User opened query 'Per CDM: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:47:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'unknown'	Etza Peters (b) (4)	29 Mar 2021 21:11:48
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'unknown'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'once (ONCE)'	(b) (4) Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Other (OTHER)'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'joint'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '22 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '22 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User entered empty.	System	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User entered empty.	System	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:02:48
User entered empty.	System	29 Mar 2021 21:11:48

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, PRODUCT: TERBINAFINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 08:38:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:38:34
Data point term sent to Coder	System	29 Mar 2021 21:13:30
User entered 'Terbinafine'	Etza Peters (b) (4) (b) (4)	29 Mar 2021 21:12:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Worsening Toe Fungal Infection'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '250'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '25 Mar 2021'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	29 Mar 2021 21:12:55
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 21:12:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 21:12:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:44:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 21:12:55

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:44:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:18
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 20:20:12

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:44:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered '15 Sep 2020'	Etza Peters (b) (4)	18 Sep 2020 20:20:27
	(b) (4)	

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:44:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered 'MRI'	Etza Peters (b) (4)	18 Sep 2020 20:20:27
	(b) (4)	

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:44:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 08:31:59
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:24:24
User entered 'Adverse Event (AE)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:20:27

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:44:42

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:20:27
	(b) (4)	

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:44:42

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User entered '18 Sep 2020'	Kathy Stephens (b) (4)	17 Nov 2020 01:52:59

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:44:42

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 01:53:46
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Nov 2020 01:53:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Nov 2020 01:52:59
	Kathy Stephens (b) (4)	17 Nov 2020 01:52:59
	(b) (4)	

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:44:42

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:46:20
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 09:35:55
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'DONE' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Nov 2020 19:25:47
User entered 'AE #2' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	19 Nov 2020 19:25:41
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:04:16
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	17 Nov 2020 01:54:32
User entered 'unresolved Ulnar nerve irritation' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:54:32
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	17 Nov 2020 01:53:46
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:52:59