

US3532020 (Prod: Children's Healthcare of Atlanta)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:34:48

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US3532020

Form: Participant Creation

Generated On: 26 Nov 2020 09:34:48

[Participant ID](#)

US3532020

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

US3532020

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:34:48

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:34:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:48

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:34:48

Condition	GLAUCOMA-BILATERAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:34:48

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 ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

Condition	VISUAL MIGRAINES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (5)

Generated On: 26 Nov 2020 09:34:48

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

Condition	CAESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:34:48

Condition	RHINOPLASTY
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:34:48

Condition	ABNOMINAL FLOATING GAS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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)

Generated On: 26 Nov 2020 09:34:48

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (12)

Generated On: 26 Nov 2020 09:34:48

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐
	No ☐
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: Vital Signs

Generated On: 26 Nov 2020 09:34:48

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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

Generated On: 26 Nov 2020 09:34:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 09:34:48

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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:34:48

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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 ☒

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Yes ☐	
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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: Injection Pain_Day(16)

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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: Injection Pain_Day(56)

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 18

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

No ☒

Yes ☐

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 20

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

No ☒

Yes ☐

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 23

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

No ☐

Yes ☐

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 25

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

No ☒

Yes ☐

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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 26

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

No ☒

Yes ☐

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 38
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 39

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

No ☒

Yes ☐

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 40
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 41
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 42
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 44
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 45
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 46
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 47
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 48
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 49
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 50
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 51
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 52
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 54

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

No ☐

Yes ☐

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 55
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 56

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

No ☐

Yes ☐

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: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	18 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:34:48

Collection date (*dd MMM yyyy*)

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

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 215

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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20 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

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

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27 APR 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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

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22 JUN 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:34:48

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

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03 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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24 AUG 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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14 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

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21 SEP 2022 23:59

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:34:48

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

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

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

Generated On: 26 Nov 2020 09:34:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532020

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:34:48

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3532020

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:34:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:48

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)

Generated On: 26 Nov 2020 09:34:48

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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:34:48

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	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	412 of 2260

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:34:48

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)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

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 ☒ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

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	
Route of administration	4X WEEK Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:48

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	
Route of administration	4X WEEK Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☒

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:34:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☒

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:34:48

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 ☐ Intramuscular ☒

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:34:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:34:48

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

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3532020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 14:55:03

US3532020

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 14:55:04

US3532020

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Aug 2020 16:01:01

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 14:55:05

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Age](#)

Audit	User	Time (GMT)
User closed query 'Age does not fit Date of Birth.' (Site from System).	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: 26 Nov 2020 09:34:48

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[White](#)

Audit	User	Time (GMT)
User entered '1'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

Unknown

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:48

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:14

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:03:40

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 14:55:04

US3532020

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:08:03

US3532020

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Condition

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:32:15
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).	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'	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 '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).	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 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:14:50

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

Condition

Audit	User	Time (GMT)
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. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:56:07
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. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:06
Coding entries removed.	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:01
User entered 'GLAUCOMA-bilateral' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:29:01
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. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:15:32
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.	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 18:32:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:32:55

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:32:55
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).	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

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

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 '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).	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 'Yes (Y)'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:15:15

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	21 Oct 2020 05:56:52
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. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:30:01
Data point term sent to Coder	System	19 Oct 2020 19:29:44
Coding entries removed.	Cindy Lubbers (b) (4) (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) (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. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	29 Sep 2020 11:16:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	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) (b) (4)	13 Aug 2020 18:35:20
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

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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, HLG: 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

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:33:25
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

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:26:51
User entered '0'	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 '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

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:26:51
User entered empty.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:27:22
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:26:51
User entered '0'	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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 empty.	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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 empty.	System	13 Aug 2020 18:15:30

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLT: 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, HLT: 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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:33:44
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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:33:44
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 '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:34:48

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

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:27:26
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:26:58
User entered empty.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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 '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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.	Laila Hussaini (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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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.	Laila Hussaini (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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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.	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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.	System	13 Aug 2020 18:15:51

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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: Osteoarthropathies, 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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:34:05
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).	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'	Laila Hussaini (b) (4)	13 Aug 2020 18:16:46

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:16:46

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:34:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:16:46

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:19:29
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

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:34:28
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).	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

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	22 Aug 2020 16:45:54
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) (b) (4)	13 Aug 2020 18:28:26
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1981' reason for change:	Cindy Lubbers (b) (4)	22 Aug 2020 16:45:54
Data Entry Error	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:17:51
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:17:51

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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

US3532020

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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) (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)	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
User entered 'Rhinoplasty' reason for change: Data Entry Error	Cindy Lubbers (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 'rhinology' reason for change: Data Entry Error	Laila Hussaini (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)	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)	13 Aug 2020 18:20:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:20:34
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

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:35:16
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).	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	22 Aug 2020 16:46:41
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 entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:18:40

US3532020

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1996' reason for change:	Cindy Lubbers (b) (4)	22 Aug 2020 16:46:41
Data Entry Error	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 18:18:40
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:18:40

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	19 Oct 2020 19:32:12
Coding entries removed.	Cindy Lubbers (b) (4)	19 Oct 2020 19:32:07
User entered 'Abnominal floating GAS' reason for change: Data Entry Error	Cindy Lubbers (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)	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)	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
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	System	13 Aug 2020 18:29:39

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (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 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
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
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

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 18:36:10
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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:36:10
User entered '0'	(b) (4) Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:36:03
User opened query 'Data is required. Please complete.' (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 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 18:29:36
User entered 'un Oct 2011'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:20:14

US3532020

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Condition

Audit	User	Time (GMT)
User closed query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' (Site from DM).	(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

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1999' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (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) (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
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:26:37
User entered 'un Oct 2011'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

Start date completely unknown

Audit	User	Time (GMT)
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	08 Sep 2020 22:49:36
User entered '0' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	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).	(b) (4) System	08 Sep 2020 22:49:21
User closed query 'Per CDM: As data entered in error keep data field blank.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 15:53:03
Query 'Per CDM: As data entered in error keep data field blank.' answered with 'Entered line in error' (Site from DM).	Cindy Lubbers (b) (4)	28 Aug 2020 20:18:50
User opened query 'Per CDM: As data entered in error keep data field blank.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 09:54:50
User entered '1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:07:44
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 '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User		Time (GMT)
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
DataPoint inactivated with code reason code Data not required.	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:26:37
User entered 'un Oct 2011'	Laila Hussaini (b) (4)	(b) (4)	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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 '0'	Laila Hussaini (b) (4)	13 Aug 2020 18:20:56

US3532020

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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 (12)

Generated On: 26 Nov 2020 09:34:48

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:22:07
Query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' answered with 'Please inactivate' (Site from DM).	Cindy Lubbers (b) (4)	08 Sep 2020 22:50:42
User opened query 'Per CDM : Response noted; please have this form inactivated by the monitor. Thank you.' (Site from DM).	(b) (4)	
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 15:55:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:54:34
Query 'Data is required. Please complete.' answered with 'Entered line in error' (Site from System).	Cindy Lubbers (b) (4)	28 Aug 2020 20:19:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	28 Aug 2020 20:19:17
	Cindy Lubbers (b) (4)	28 Aug 2020 20:19:17
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
Query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:54:41
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	28 Aug 2020 20:19:17
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:19:17

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:54:48
Query 'Data is required. Please complete.' answered with 'Entered line in error' (Site from System).	Cindy Lubbers (b) (4)	28 Aug 2020 20:19:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Aug 2020 20:19:17
User entered empty.	System	28 Aug 2020 20:19:17
	Cindy Lubbers (b) (4)	28 Aug 2020 20:19:17
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 20:19:17

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '11:44'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:44'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '167' cm	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: 26 Nov 2020 09:34:48

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '82.1' kg	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: 26 Nov 2020 09:34:48

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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)	26 Aug 2020 02:08:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (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)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered '66'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered '18'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered '129'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 02:08:37
User entered '84'	Cindy Lubbers (b) (4)	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 16:12:16

US3532020

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:36

US3532020

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:36

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[If No, what is the reason?](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 1999' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:41:42
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:34:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:40:49

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Other](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 16:43:00
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).	System	13 Aug 2020 16:42:44
User entered empty.	Cindy Lubbers (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:48

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:42:44

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Aug 2020 16:43:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	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) [REDACTED]	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 16:19:21

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 18:22:42

US3532020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:48

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 14:44:23
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 09:34:48

Height

Audit	User	Time (GMT)
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) (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)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (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)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:48

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:48

Height

Audit	User	Time (GMT)
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) (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)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (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)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:48

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	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: 26 Nov 2020 09:34:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:44'	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: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	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: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	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: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	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: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	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: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:48

Height

Audit	User	Time (GMT)
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) (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)	28 Aug 2020 20:21:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(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)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:48

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:20:52
User entered '82.1' kg	Cindy Lubbers (b) (4)	13 Aug 2020 16:46:32

US3532020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:37:29
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).	System	13 Aug 2020 16:46:32
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: 26 Nov 2020 09:34:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020' 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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:38:23
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 18:37:29
User entered '13:22' 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: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F 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: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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).	System	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: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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).	System	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: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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).	System	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: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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).	System	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: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:43:47

US3532020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:43:47

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:48'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:48'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:04:55

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:25'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 16:47:02

US3532020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	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: 26 Nov 2020 09:34:48

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:15'	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: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:03:49
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).	System	13 Aug 2020 17:03:43
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: 26 Nov 2020 09:34:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:03:43

US3532020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	13 Aug 2020 17:03:54

US3532020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:03:54

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:04
User entered 'Yes (Y)'	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:04
User entered '97.6'	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:04
User entered 'No (N)'	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:04
User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:26:04

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:15:05
User entered 'Yes (Y)'	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:15:05
User entered '97.1'	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:15:05
User entered '14 Aug 2020 10:15'	System	14 Aug 2020 14:15:05

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:43:53
User entered 'Yes (Y)'	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:43:53
User entered '97.2'	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:43:53
User entered 'No (N)'	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:43:53
User entered '14 Aug 2020 20:43'	System	15 Aug 2020 00:43:53

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:56:11
User entered '97.7'	System	15 Aug 2020 21:56:11

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:24
User entered 'Yes (Y)'	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:24
User entered '98.2'	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:24
User entered 'No (N)'	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:24
User entered '16 Aug 2020 18:13'	System	16 Aug 2020 22:13:24

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:38:56
User entered 'Yes (Y)'	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:38:56
User entered '98.5'	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:38:56
User entered 'No (N)'	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:38:56
User entered '17 Aug 2020 18:38'	System	17 Aug 2020 22:38:56

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:53:03
User entered '97.9'	System	18 Aug 2020 23:53:03

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:02:15
User entered 'Yes (Y)'	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:02:15
User entered '97.5'	System	19 Aug 2020 23:02:15

US3532020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:50
User entered 'None (1)'	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:50
User entered 'No (N)'	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:50
User entered 'No (N)'	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:50
User entered 'None (1)'	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:26:50
User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:26:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:18:11
User entered 'No (N)'	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:18:11
User entered 'No (N)'	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:18:11
User entered '14 Aug 2020 10:18'	System	14 Aug 2020 14:18:11

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:45:50
User entered 'No (N)'	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:45:50
User entered 'Yes (Y)'	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:48

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)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:45:50
User entered '14 Aug 2020 20:45'	System	15 Aug 2020 00:45:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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)
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' User entered '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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:57:16
User entered 'None (1)'	System	15 Aug 2020 21:57:16

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:39:48
User entered 'No (N)'	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:39:48
User entered 'No (N)'	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:39:48
User entered 'None (1)'	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Aug 2020 22:39:48
User entered '17 Aug 2020 18:39'	System	17 Aug 2020 22:39:48

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:51:57
User entered 'No (N)'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:51:57
User entered 'No (N)'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:51:57
User entered 'None (1)'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:51:57
User entered '18 Aug 2020 19:51'	System	18 Aug 2020 23:51:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:03
User entered '19 Aug 2020 19:01'	System	19 Aug 2020 23:01:03

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered 'No (N)'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	13 Aug 2020 17:27:44
User entered '13 Aug 2020 13:27'	System	13 Aug 2020 17:27:44

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered 'None (0)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered 'None (0)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered 'None (0)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered 'None (0)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered 'No (N)'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Aug 2020 14:19:39
User entered '14 Aug 2020 10:19'	System	14 Aug 2020 14:19:39

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered 'None (0)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered 'None (0)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered 'None (0)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered 'None (0)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered 'No (N)'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Aug 2020 00:48:38
User entered '14 Aug 2020 20:48'	System	15 Aug 2020 00:48:38

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered 'None (0)'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Aug 2020 21:58:08
User entered '15 Aug 2020 17:58'	System	15 Aug 2020 21:58:08

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'None (0)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered 'No (N)'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Aug 2020 22:13:58
User entered '16 Aug 2020 18:13'	System	16 Aug 2020 22:13:58

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'None (0)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered 'No (N)'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:52:37
User entered '18 Aug 2020 19:52'	System	18 Aug 2020 23:52:37

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

HEADACHE

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

FATIGUE

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

CHILLS

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'None (0)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered 'No (N)'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Aug 2020 23:01:30
User entered '19 Aug 2020 19:01'	System	19 Aug 2020 23:01:30

US3532020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 04:26:54
User entered '21 Aug 2020 00:26'	System	21 Aug 2020 04:26:54

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 04:04:50
User entered '22 Aug 2020 00:04'	System	22 Aug 2020 04:04:50

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	23 Aug 2020 12:22:39
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 12:22:39
User entered '23 Aug 2020 08:22'	System	23 Aug 2020 12:22:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 04:58:22
User entered '24 Aug 2020 00:58'	System	24 Aug 2020 04:58:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Aug 2020 02:23:47
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 02:23:47
User entered '24 Aug 2020 22:23'	System	25 Aug 2020 02:23:47

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(12)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 04:38:53
User entered '26 Aug 2020 00:34'	System	26 Aug 2020 04:38:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(13)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:11:06
User entered '26 Aug 2020 21:10'	System	27 Aug 2020 01:11:06

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(14)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 05:19:26
User entered '30 Aug 2020 01:19'	System	30 Aug 2020 05:19:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(17)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 23:24:46
User entered '30 Aug 2020 19:24'	System	30 Aug 2020 23:24:46

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(18)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Sep 2020 21:05:26
User entered '02 Sep 2020 17:05'	System	02 Sep 2020 21:05:26

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(21)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 00:53:41
User entered '03 Sep 2020 20:53'	System	04 Sep 2020 00:53:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(22)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	05 Sep 2020 20:50:24
User entered '05 Sep 2020 16:50'	System	05 Sep 2020 20:50:24

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(24)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 06:05:35
User entered '08 Sep 2020 02:05'	System	08 Sep 2020 06:05:35

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(26)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 04:49:17
User entered '09 Sep 2020 00:49'	System	09 Sep 2020 04:49:17

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(27)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 18:20:37
User entered '09 Sep 2020 14:20'	System	09 Sep 2020 18:20:37

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(28)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 17:38:09
User entered '10 Sep 2020 13:38'	System	10 Sep 2020 17:38:09

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(29)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 19:42:42
User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:42

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(30)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 02:48:22
User entered '12 Sep 2020 22:48'	System	13 Sep 2020 02:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(31)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 22:41:41
User entered '13 Sep 2020 18:41'	System	13 Sep 2020 22:41:41

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(32)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:02:19
User entered '14 Sep 2020 14:02'	System	14 Sep 2020 18:02:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(33)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 17:46:39
User entered '16 Sep 2020 13:46'	System	16 Sep 2020 17:46:39

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(35)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 21:42:53
User entered '17 Sep 2020 17:42'	System	17 Sep 2020 21:42:53

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(36)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 03:07:29
User entered '18 Sep 2020 23:07'	System	19 Sep 2020 03:07:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(37)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 20:48:04
User entered '19 Sep 2020 16:47'	System	19 Sep 2020 20:48:04

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(38)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 04:33:23
User entered '21 Sep 2020 00:33'	System	21 Sep 2020 04:33:23

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(39)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 15:34:52
User entered '23 Sep 2020 11:34'	System	23 Sep 2020 15:34:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(41)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 16:48:22
User entered '26 Sep 2020 12:48'	System	26 Sep 2020 16:48:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(45)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 20:29:22
User entered '27 Sep 2020 16:29'	System	27 Sep 2020 20:29:22

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(46)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 21:20:30
User entered '28 Sep 2020 17:20'	System	28 Sep 2020 21:20:30

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(47)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 00:23:52
User entered '30 Sep 2020 19:23'	System	01 Oct 2020 00:23:52

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(49)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 23:03:12
User entered '01 Oct 2020 18:03'	System	01 Oct 2020 23:03:12

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(50)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Oct 2020 16:53:29
User entered '03 Oct 2020 11:53'	System	03 Oct 2020 16:53:29

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(51)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Oct 2020 00:17:57
User entered '03 Oct 2020 19:17'	System	04 Oct 2020 00:17:57

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(52)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Oct 2020 20:19:49
User entered '04 Oct 2020 15:19'	System	04 Oct 2020 20:19:49

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(53)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Oct 2020 04:09:19
User entered '06 Oct 2020 23:09'	System	07 Oct 2020 04:09:19

US3532020

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(55)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 04:28:34
User entered '21 Aug 2020 00:28'	System	21 Aug 2020 04:28:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 12:22:45
User entered 'No (N)'	System	23 Aug 2020 12:22:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 12:22:45
User entered '23 Aug 2020 08:22'	System	23 Aug 2020 12:22:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 04:58:37
User entered 'No (N)'	System	24 Aug 2020 04:58:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 04:58:37
User entered '24 Aug 2020 00:58'	System	24 Aug 2020 04:58:37

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	25 Aug 2020 02:23:58
User entered 'No (N)'	System	25 Aug 2020 02:23:58

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 02:23:58
User entered '24 Aug 2020 22:23'	System	25 Aug 2020 02:23:58

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 04:38:57
User entered 'No (N)'	System	26 Aug 2020 04:38:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 04:38:57
User entered '26 Aug 2020 00:34'	System	26 Aug 2020 04:38:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:11:10
User entered 'No (N)'	System	27 Aug 2020 01:11:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:11:10
User entered '26 Aug 2020 21:10'	System	27 Aug 2020 01:11:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	28 Aug 2020 01:00:45
User entered 'No (N)'	System	28 Aug 2020 01:00:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 01:00:45
User entered '27 Aug 2020 21:00'	System	28 Aug 2020 01:00:45

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	29 Aug 2020 03:11:35
User entered 'No (N)'	System	29 Aug 2020 03:11:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Aug 2020 03:11:35
User entered '28 Aug 2020 23:11'	System	29 Aug 2020 03:11:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 05:19:34
User entered 'No (N)'	System	30 Aug 2020 05:19:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 05:19:34
User entered '30 Aug 2020 01:19'	System	30 Aug 2020 05:19:34

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	01 Sep 2020 03:54:42
User entered 'No (N)'	System	01 Sep 2020 03:54:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	02 Sep 2020 03:08:11
User entered 'No (N)'	System	02 Sep 2020 03:08:11

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Sep 2020 03:08:11
User entered '01 Sep 2020 23:08'	System	02 Sep 2020 03:08:11

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 00:53:51
User entered 'No (N)'	System	04 Sep 2020 00:53:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 00:53:51
User entered '03 Sep 2020 20:53'	System	04 Sep 2020 00:53:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	05 Sep 2020 20:50:29
User entered '05 Sep 2020 16:50'	System	05 Sep 2020 20:50:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	07 Sep 2020 00:15:17
User entered 'No (N)'	System	07 Sep 2020 00:15:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 00:15:17
User entered '06 Sep 2020 20:15'	System	07 Sep 2020 00:15:17

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 06:05:40
User entered 'No (N)'	System	08 Sep 2020 06:05:40

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 06:05:40
User entered '08 Sep 2020 02:05'	System	08 Sep 2020 06:05:40

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 04:49:26
User entered 'No (N)'	System	09 Sep 2020 04:49:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 04:49:26
User entered '09 Sep 2020 00:49'	System	09 Sep 2020 04:49:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 18:20:44
User entered '09 Sep 2020 14:20'	System	09 Sep 2020 18:20:44

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	10 Sep 2020 17:39:01
User entered 'No (N)'	System	10 Sep 2020 17:39:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	13 Sep 2020 02:48:29
User entered 'No (N)'	System	13 Sep 2020 02:48:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 02:48:29
User entered '12 Sep 2020 22:48'	System	13 Sep 2020 02:48:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	13 Sep 2020 22:41:47
User entered 'No (N)'	System	13 Sep 2020 22:41:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 22:41:47
User entered '13 Sep 2020 18:41'	System	13 Sep 2020 22:41:47

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:45:14
User entered 'Yes (Y)'	System	15 Sep 2020 16:45:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:45:14
User entered '15 Sep 2020 12:45'	System	15 Sep 2020 16:45:14

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 17:46:51
User entered 'Yes (Y)'	System	16 Sep 2020 17:46:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 17:46:51
User entered '16 Sep 2020 13:46'	System	16 Sep 2020 17:46:51

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 21:43:02
User entered 'No (N)'	System	17 Sep 2020 21:43:02

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 21:43:02
User entered '17 Sep 2020 17:43'	System	17 Sep 2020 21:43:02

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	19 Sep 2020 03:07:42
User entered 'No (N)'	System	19 Sep 2020 03:07:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 03:07:42
User entered '18 Sep 2020 23:07'	System	19 Sep 2020 03:07:42

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	19 Sep 2020 20:48:10
User entered 'No (N)'	System	19 Sep 2020 20:48:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 20:48:10
User entered '19 Sep 2020 16:48'	System	19 Sep 2020 20:48:10

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 04:33:30
User entered '21 Sep 2020 00:33'	System	21 Sep 2020 04:33:30

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(39)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 12:36:31
User entered '22 Sep 2020 08:36'	System	22 Sep 2020 12:36:31

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(40)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 15:34:57
User entered 'No (N)'	System	23 Sep 2020 15:34:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 15:34:57
User entered '23 Sep 2020 11:34'	System	23 Sep 2020 15:34:57

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(41)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 18:32:29
User entered '25 Sep 2020 14:32'	System	25 Sep 2020 18:32:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(44)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 16:48:26
User entered 'No (N)'	System	26 Sep 2020 16:48:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 16:48:26
User entered '26 Sep 2020 12:48'	System	26 Sep 2020 16:48:26

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(45)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 20:29:29
User entered 'No (N)'	System	27 Sep 2020 20:29:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 20:29:29
User entered '27 Sep 2020 16:29'	System	27 Sep 2020 20:29:29

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(46)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 21:20:35
User entered '28 Sep 2020 17:20'	System	28 Sep 2020 21:20:35

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(47)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	01 Oct 2020 00:24:01
User entered 'No (N)'	System	01 Oct 2020 00:24:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 00:24:01
User entered '30 Sep 2020 19:23'	System	01 Oct 2020 00:24:01

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(49)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	01 Oct 2020 23:03:18
User entered 'No (N)'	System	01 Oct 2020 23:03:18

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 23:03:18
User entered '01 Oct 2020 18:03'	System	01 Oct 2020 23:03:18

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(50)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	03 Oct 2020 16:53:36
User entered 'No (N)'	System	03 Oct 2020 16:53:36

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(51)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	04 Oct 2020 00:18:03
User entered 'No (N)'	System	04 Oct 2020 00:18:03

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(52)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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'	System	07 Oct 2020 04:09:24
User entered 'No (N)'	System	07 Oct 2020 04:09:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 26 Nov 2020 09:34:48

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Oct 2020 04:09:24
User entered '06 Oct 2020 23:09'	System	07 Oct 2020 04:09:24

US3532020

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(55)

Generated On: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:52

US3532020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	20 Aug 2020 15:22:59

US3532020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:22:59

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	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)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:23:23

US3532020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:24:44

US3532020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 23:24:44

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:26

US3532020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 23:27:36

US3532020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 23:27:36

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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) (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)	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).	(b) (4)	
User entered '18 Sep 2020'	System	18 Sep 2020 19:25:54
	Etza Peters (b) (4)	18 Sep 2020 19:25:54
	(b) (4)	

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	18 Sep 2020 19:25:54

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	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: 26 Nov 2020 09:34:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:57'	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: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97' F	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: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	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: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '139'	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: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	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: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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) (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)	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)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 10:43:25
	Etza Peters (b) (4)	18 Sep 2020 19:29:56
	(b) (4)	

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:29:56

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:26:51

US3532020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:26:51

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete dosing discontinuation page under end of study folder.' (Site from DM).	(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)	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)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:27:21

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:00'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:27:38

US3532020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	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).	System	18 Sep 2020 19:27:52
User entered '18 Sep 2020'	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: 26 Nov 2020 09:34:48

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:27:52

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 19:28:16

US3532020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:28:16

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:39

US3532020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 14:39:43

US3532020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:39:43

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:56:24
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: 26 Nov 2020 09:34:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' 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)	12 Oct 2020 20:29:29
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	12 Oct 2020 20:29:06

US3532020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	12 Oct 2020 20:29:06

US3532020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:55:33

US3532020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 13:55:33

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:32

US3532020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 13:58:36

US3532020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 13:58:36

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 16:31:37

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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).	System	23 Oct 2020 16:33:01
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: 26 Nov 2020 09:34:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:38'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '142'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '92'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 16:33:01

US3532020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:34:54

US3532020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:34:54

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:47'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:35:14

US3532020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	23 Oct 2020 16:35:19

US3532020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:35:19

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[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: '2020-10-13T00:01:40', 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: 26 Nov 2020 09:34:48

Have you been exposed to someone with 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: '2020-10-13T00:01:49', 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: 26 Nov 2020 09:34:48

[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: '2020-10-13T00:01:59', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '9befbd55-22a3-49f3-9fa6-016374122e3e'	System	13 Oct 2020 04:02:02
User entered '13 Oct 2020 00:01:59'	System	13 Oct 2020 04:02:02

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[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: '2020-10-20T19:46:59', 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: 26 Nov 2020 09:34:48

Have you been exposed to someone with 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: '2020-10-20T19:47:04', 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: 26 Nov 2020 09:34:48

[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: '2020-10-20T19:47:08', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '97603fd4-bf05-42c8-b2b6-e0c92b05e585'	System	20 Oct 2020 23:47:12
User entered '20 Oct 2020 19:47:08'	System	20 Oct 2020 23:47:12

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[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: '2020-10-27T01:13:07', 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: 26 Nov 2020 09:34:48

Have you been exposed to someone with 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: '2020-10-27T01:13:12', 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: 26 Nov 2020 09:34:48

[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: '2020-10-27T01:13:15', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: '57ca8504-3be8-4185-ba98-986b57506c71'	System	27 Oct 2020 05:13:17
User entered '27 Oct 2020 01:13:15'	System	27 Oct 2020 05:13:17

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

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: '2020-11-17T01:03:07', 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: 26 Nov 2020 09:34:48

Have you been exposed to someone with 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: '2020-11-17T01:03:13', 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: 26 Nov 2020 09:34:48

[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: '2020-11-17T01:03:18', User OID: 'PatientReportedOutcome (US3532020)', ODM File OID: 'df87f6aa-b672-4cb8-8b14-cededc394ba8'	System	17 Nov 2020 06:03:24
User entered '17 Nov 2020 01:03:18'	System	17 Nov 2020 06:03:24

US3532020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 Oct 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: 26 Nov 2020 09:34:48

[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 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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 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: 26 Nov 2020 09:34:48

[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 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: 26 Nov 2020 09:34:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:57:27
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 05:57:27

US3532020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:48

[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 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: 26 Nov 2020 09:34:48

[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 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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 22:30:06

US3532020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:36:33

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	20 Oct 2020 18:30:41
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 18:30:41
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) (b) (4)	09 Sep 2020 18:39:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 18:39:56
Data point term sent to Coder	System	09 Sep 2020 18:39:33
User entered 'Soreness at injection site'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
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) (b) (4)	09 Sep 2020 18:41:44
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) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:13:58
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Aug 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:13:58
User entered empty.	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

End time (00:00-23:59)

Audit	User	Time (GMT)
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
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 20:13:58
User entered empty.	System	18 Sep 2020 20:13:58
	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40
	(b) (4)	

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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) (b) (4)	09 Sep 2020 18:43:18
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) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[None](#)

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from 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 '1'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Sep 2020 18:43:18
User entered '1'	(b) (4) Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:13:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cindy Lubbers (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 18:38:40

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	29 Sep 2020 05:01:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:01:53
Data point term sent to Coder	System	18 Sep 2020 20:16:32
User entered 'Ulnar Nerve Irritation'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:07:01
User entered 'Yes (Y)'	Etza Peters (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 19:07:01
User entered empty.	Etza Peters (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

Action taken with investigational product

Audit	User	Time (GMT)
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) (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)	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

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

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: 26 Nov 2020 09:34:48

[None](#)

Audit	User	Time (GMT)
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) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:16:48
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 19:07:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:16:02

US3532020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:16:02

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:34:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:20:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	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)	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)	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:37:06
User entered 'Medical hx # 1'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '88'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	02 Nov 2020 20:03:13
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. ' (Site from DM).	(b) (4)	
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. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 10:46:33
User entered 'Other (OTHER)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 19:43:02
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. ' (Site from DM).	(b) (4)	
User entered 'mg (mg)'	Cindy Lubbers (b) (4)	26 Sep 2020 19:42:50
	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 06:52:29
	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
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) (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)	02 Nov 2020 20:03:23
User entered empty; reason for change Data Entry Error	(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)	26 Sep 2020 19:42:50
User entered empty.	Laila Hussaini (b) (4)	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:24:24

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	27 Sep 2020 13:13:40
Data point term sent to Coder Coding entries removed.	System	26 Sep 2020 19:44:26
	Cindy Lubbers (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)	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)	08 Sep 2020 06:59:47
Data point term sent to Coder Coding entries removed.	System	07 Sep 2020 18:27:57
	Cindy Lubbers (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)	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)	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)	13 Aug 2020 19:27:08
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
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) (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)	26 Sep 2020 19:44:24
User entered 'GLAUCOMA both eyes' reason for change: New Information	Cindy Lubbers (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)	13 Aug 2020 19:37:41
User entered 'medical hx # 2'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Drop'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
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) (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)	07 Sep 2020 18:29:37
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Cindy Lubbers (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)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	07 Sep 2020 18:27:43
User entered 'Ophthalmic'	Laila Hussaini (b) (4)	13 Aug 2020 19:27:08

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Separate Dosage 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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	13 Aug 2020 19:27:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:55

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:48

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per MM: Please clarify the reported CM term.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:53:28
Query 'Per MM: Please clarify the reported CM term.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4)	07 Sep 2020 18:32:08
User opened query 'Per MM: Please clarify the reported CM term.' (Site from DM).	(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
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 20:25:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
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
DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF.	(b) (4)	
' 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
User opened query '	Coder Import (b) (4)	14 Aug 2020 06:09:09
DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF.	(b) (4)	
' (Site from System).		
Data point term sent to Coder	System	13 Aug 2020 19:38:35
Data point term sent to Coder	System	13 Aug 2020 19:29:15

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Allere'	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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis' reason for change: New Information	Laila Hussaini (b) (4)	13 Aug 2020 19:38:19
User entered 'medical hx # 3'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
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) (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)	26 Sep 2020 19:48:20
User entered '220' reason for change: Data Entry Error	(b) (4)	26 Sep 2020 19:48:07
User entered '229' reason for change: Data Entry Error	Cindy Lubbers (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)	13 Aug 2020 19:28:53

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	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).	(b) (4)	
User entered empty.	System	13 Aug 2020 19:28:53
	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (b) (4)	13 Aug 2020 19:40:09
Data point term sent to Coder Coding entries removed.	System Laila Hussaini (b) (4) (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) (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) (b) (4)	13 Aug 2020 19:31:08
Data point term sent to Coder User entered 'Allegra'	System Laila Hussaini (b) (4) (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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:38:44
User entered 'medical hx # 5'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	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) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	13 Aug 2020 19:29:32

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
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) (b) (4)	28 Aug 2020 20:25:33
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) (b) (4)	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	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)	13 Aug 2020 19:30:46

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	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)	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)	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'General Health'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'unk'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'occasionally'	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	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) (b) (4)	13 Aug 2020 19:31:41

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'unk'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:36:29
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) (b) (4)	13 Aug 2020 19:36:13

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	13 Aug 2020 19:36:29
User entered '0'	(b) (4) 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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'UNK'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Aug 2020 20:26:41
User entered 'No (N)'	Laila Hussaini (b) (4)	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	13 Aug 2020 19:42:06

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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, PRODUCTSYNONYM: SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (b) (4)	22 Aug 2020 16:50:11
Data point term sent to Coder Coding entries removed.	System Cindy Lubbers (b) (4) (b) (4)	22 Aug 2020 16:49:56 22 Aug 2020 16:49:37
User entered 'simethicone' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (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) (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) (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) (b) (4)	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gas'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '125'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '4x week'	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	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)	13 Aug 2020 19:44:45

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gas'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	22 Aug 2020 16:51:44
User entered '100'	Laila Hussaini (b) (4)	13 Aug 2020 19:45:42

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '4x week'	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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).	System	18 Sep 2020 19:36:25
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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'ULNAr NERVE IRRITATION' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:18:14
User entered 'Ulna Nerve Irritation' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:09:11
User entered 'Pain at injection site'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unknown'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'unknown'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)' reason for change:	Etza Peters (b) (4)	18 Sep 2020 19:41:44
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	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) (b) (4)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
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) (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)	02 Nov 2020 20:02:29
User entered 'No (N)' reason for change: Data Entry Error	(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)	18 Sep 2020 19:36:25

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	02 Nov 2020 20:00:57
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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:18:14
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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).	System	18 Sep 2020 19:42:52
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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
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) (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)	04 Nov 2020 21:55:02
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (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)	18 Sep 2020 19:42:52

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	04 Nov 2020 21:54:53
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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	18 Sep 2020 20:18:38
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, PRODUCT: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'un Jun 2020'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: STEROIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1988'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[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: 26 Nov 2020 09:34:48

[Name of Medication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3532020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:34:48

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:34:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:34:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'INJECTION'	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: 26 Nov 2020 09:34:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:34:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'YEARLY'	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: 26 Nov 2020 09:34:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 09:34:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	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: 26 Nov 2020 09:34:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:34:48

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	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: 26 Nov 2020 09:34:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:34:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 23:05:19

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:34:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:20:12

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:48

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:20:27

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'MRI'	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:20:27

US3532020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:48

[Indication](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:34:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	18 Sep 2020 20:20:27

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:48

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:52:59

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 01:53:46
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) (b) (4)	17 Nov 2020 01:53:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 01:52:59
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:52:59

US3532020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:48

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

Audit	User	Time (GMT)
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(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