

US3202070 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:43:46

All time stamps listed in this document are displayed in GMT

US3202070

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

[Participant ID](#)

US3202070

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

US3202070

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

Visit date (dd MMM yyyy)	08 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3202070

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	48
Age Units	YEARS
Age (Derived)	48
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:53:25

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	1 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	3 JAN 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	3 JAN 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3202070

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	UTERINE ABLATION- IRREGULAR PERIODS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	MULTIPLE SCLEROSIS
Start date (dd MMM yyyy)	1 DEC 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	INSULIN RESISTANCE
Start date (dd MMM yyyy)	1 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202070

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	1 JUN 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202070

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	ANXIETY
Start date (dd MMM yyyy)	1 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202070

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	1 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202070

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Condition	OBESITY (BMI- 33.5)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202070

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:36
Height (<i>xxx.x</i>)	153 cm
Weight (<i>xxx.x</i>)	78.5 kg
BMI (<i>xxx.x</i>)	33.53411 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*) 8 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*) 3 JAN 2003

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

CLAIMS ASSISTANT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:53:25

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

Visit date (dd MMM yyyy)	08 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 102190

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Height	ND - Not Done
Weight	ND - Not Done

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:36
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 11:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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) 08 AUG 2020

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 11:03

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 AUG 2020
Collection time (00:00-23:59)	10:43 (24 HR)
Collection date and time (derived)	8 AUG 2020 10:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	8 AUG 2020 10:40
Nasopharyngeal Swab 2	No		

US3202070

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 11:31

PC Open Date & Time

08 AUG 2020 11:23

PC Close Date & Time

08 AUG 2020 13:53

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	08 AUG 2020 17:12
PC Open Date & Time	08 AUG 2020 14:48
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

97.5 °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

09 AUG 2020 12:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 20:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

12 AUG 2020 17:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 AUG 2020 17:11

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 AUG 2020 00:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 01:04

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 11:32

PC Open Date & Time

08 AUG 2020 11:23

PC Close Date & Time

08 AUG 2020 13:53

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

08 AUG 2020 17:13

PC Open Date & Time

08 AUG 2020 14:48

PC Close Date & Time

09 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

11 AUG 2020 20:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

12 AUG 2020 17:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

13 AUG 2020 17:11

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

15 AUG 2020 00:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 11:39
PC Open Date & Time	08 AUG 2020 11:23
PC Close Date & Time	08 AUG 2020 13:53

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 17:14
PC Open Date & Time	08 AUG 2020 14:48
PC Close Date & Time	09 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:02
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:12
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 00:49
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 17 AUG 2020 01:05

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 17 AUG 2020 01:05

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 AUG 2020 07:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:02

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 AUG 2020 01:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 07:25
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 12:02
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments NO ANSWER

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

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 NO ANSWER

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 16:28
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	18:01 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 18:01
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 17:22 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 17:22

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

US3202070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	17:03 (24 HR)
Collection date and time (derived)	14 SEP 2020 17:03

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:05

PC Open Date & Time

14 SEP 2020 17:42

PC Close Date & Time

14 SEP 2020 20:12

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 SEP 2020 21:31
PC Open Date & Time	14 SEP 2020 21:07
PC Close Date & Time	15 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 06:06

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 07:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 06:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

98.2 °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

19 SEP 2020 11:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 09:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

21 SEP 2020 06:39

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:06

PC Open Date & Time

14 SEP 2020 17:42

PC Close Date & Time

14 SEP 2020 20:12

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:31

PC Open Date & Time

14 SEP 2020 21:07

PC Close Date & Time

15 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 06:06

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 07:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 07:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 11:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 09:10

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 06:40

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 18:06
PC Open Date & Time	14 SEP 2020 17:42
PC Close Date & Time	14 SEP 2020 20:12

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 21:32
PC Open Date & Time	14 SEP 2020 21:07
PC Close Date & Time	15 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 06:07
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 07:22
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 07:11
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 11:55
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 09:10
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

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 ☒

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 06:40
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:24

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	16:12 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 16:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

16:20 (24 HR)

Collection date and time (derived)

12 OCT 2020 16:20

US3202070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:53:25

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

12 OCT 2020 21:19:33

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

15 OCT 2020 03:13:47

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 05:52:42

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

12 NOV 2020 00:54:00

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 06:17:29

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

23 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 12:06:42

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 01:05:04
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 02:04:11

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 13:16:33

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 01:03:40

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☒

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

Date and time of submission

25 JAN 2021 00:24:26

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 00:25:24

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 01:02:15

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 01:30:46

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 05:35:19

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 01:44:02

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 00:41:42

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 05:43:26

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 03:43:40

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 16:15:34

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 02:12:50

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 SEP 2021 00:01
Patient Cloud Close Date & Time	24 SEP 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

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

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3202070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:43:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 01:44:46

US3202070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:38:50

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:38:50

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:30:19

Generated On: 09 Jun 2021 15:43:46

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

Visit date (dd MMM yyyy)	15 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:30:19

Generated On: 09 Jun 2021 15:43:46

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202070

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:30:19

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:30:19

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

15:48 (24 HR)

Collection date and time (derived)

15 MAR 2021 15:48

US3202070

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 15:34:18

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 15:34:18

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202070

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:43:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202070

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3202070

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3202070

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

Height	
Weight	
BMI (xxx.x)	

US3202070

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:43
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:17
Temperature (xxx.x)	35.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 13:49 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 13:49

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

US3202070

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

13:48 (24 HR)

Collection date and time (derived)

14 JAN 2021 13:48

US3202070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	13:46
Collection Date and Time (derived)	14 JAN 2021 13:46

US3202070

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

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

Visit date (dd MMM yyyy)	11 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:52
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 16:40
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202070

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 16:01 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 16:01

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

US3202070

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202070

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:29:51

Generated On: 09 Jun 2021 15:43:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202070

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202070

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

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.

US3202070

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	15:48 (24 HR)
Collection date and time (derived)	15 MAR 2021 15:48

US3202070

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:03:25

Generated On: 09 Jun 2021 15:43:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

AEID	USA-US128-2021-MRNA-1273-P30 1000011
Adverse event	RECURRENT CERVICAL DYSPLASIA (WITH HIGH RISK HPV)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	20 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

SUBJECT HAS HAD ABNORMAL
PAP X 2 SINCE 2019 SO FULL
HYSTERECTOMY COMPLETED
PER GYN RECOMMENDATION.
SAE ONLY BECAUSE OF
OVERNIGHT HOSPITALIZATION
REQUIRED FOR THIS SURGERY.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

AEID

Adverse event

BENIGN LIPOMA LEFT
BUTTOCK

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)

15 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

AEID

Adverse event

POST-SURGICAL PAIN

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)

19 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 AUG 2020
Start time (00:00-23:59)	18:00 (24 HR)
AE start date and time (derived)	08 AUG 2020 18:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 AUG 2020
End time (00:00-23:59)	09:00 (24 HR)
AE End Date and Time (derived)	18 AUG 2020 09:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:54

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

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

Yes ☒

No ☐

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

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication AUBAGIO

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 14

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication SYNJARDY XR

Prophylaxis Yes ☐
No ☒

Indication INSULIN RESISTANCE

Dose per administration 12.5/1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication DONEPEZIL HCL

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication INSULIN RESISTANCE

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication PROGESTERONE

Prophylaxis Yes ☐
No ☒

Indication HOT FLASHES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 13:29:46

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication ARMOUR THYROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JUN 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication FISH OIL

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 1400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 13:29:46

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Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU PREVENTION
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication ESTROGEN PATCH

Prophylaxis Yes ☐
No ☒

Indication HOT FLASHES

Dose per administration 0.025

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:29:46

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Name of Medication PHENTERMINE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 13:29:46

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Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication RECURRENT CERVICAL
DYSPLASIA (WITH HIGH RISK
HPV) SURGICAL MEDICATION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 13:29:46

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Name of Medication CALCIUM CITRATE/VIT D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 315/250

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

If dose unit is Other, specify MG/UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication COENZYME Q10

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCROSIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication LACTOBACILLIUS

Prophylaxis Yes ☒
No ☐

Indication POBIOTIC GUT HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication LUTEIN

Prophylaxis Yes ☒
No ☐

Indication EYE PROPHLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNK

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication JUVEDERM

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNK

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PRE-SURGICAL PAIN
PREVENTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication MARCAINE 0.5%

Prophylaxis Yes ☐
No ☒

Indication BENIGN LIPOMA LEFT
BUTTOCK

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication ANCEF (CEFAZOLIN)

Prophylaxis Yes ☒
No ☐

Indication SURGICAL PROCEDURE FOR
INFECTION PROPHYLAXIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication COLACE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
OPIOID-INDUCED
CONSTIPATION POST
SURGICAL PROCEDURE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication MARINOL

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PREVENTION PRIOR
TO SUGERY

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication NEURONTIN

Prophylaxis Yes ☒
No ☐

Indication PAIN PROPHYLAXIS
PRE-SURGERY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication NORCO (HYDROCODONE 5MG /
ACETAMINOPHEN 325MG PER
TABLET)

Prophylaxis Yes ☐
No ☒

Indication POST-SURGICAL PAIN

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication POST-SURGICAL PAIN

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒
No ☐

Indication PROCEDURAL MEDICATION
(TO MAINTAIN IV LINE)

Dose per administration 125

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒
No ☐

Indication PROCEDURAL MEDICATION TO
MAINTAIN IV

Dose per administration 100

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

Name of Medication REGLAN

Prophylaxis Yes ☒
No ☐

Indication PRE-SURGICAL NAUSEA
PREVENTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 09 Apr 2021 13:29:46

Generated On: 09 Jun 2021 15:43:46

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

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 13:29:49

Generated On: 09 Jun 2021 15:43:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 FEB 2021	TOTAL HYSTERECTOMY	Adverse Event	
19 FEB 2021	BILATERAL SALPINGO-COPHORECTOMY	Adverse Event	
19 FEB 2021	EXCISION OF L BUTTOCK LIPOMA	Adverse Event	

US3202070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:43:46

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 ☐

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 08:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 14:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 08:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 13:29:50

Generated On: 09 Jun 2021 15:43:46

SAEID	USA-US128-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 14:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202070 (Prod: WR-ClinSearch, LLC)

US3202070

Form: Participant Creation

Generated On: 09 Jun 2021 15:43:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:33:57
User entered 'US3202070'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:25

US3202070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:46:54

US3202070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:26

US3202070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:46:54

US3202070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'SCRN'	System	19 Aug 2020 19:46:54

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:27

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '48'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'YEARS'	System	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '48'	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Female (F)'	(b) (4) Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'I'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:07

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered '08 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Aug 2020'	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2020'	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:25:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:26

US3202070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'I'	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:06:55

US3202070

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:43:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:07:38

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 12:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 12:10:09
Data point term sent to Coder	System	10 Aug 2020 12:09:28
User entered 'Seasonal Allergies'	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Jan 2020'	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2020'	System	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2020'	System	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	10 Aug 2020 12:08:30

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition #9 HYPOTHYROIDISM (01 JUN 2003-ONGOING). If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:19:52
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:39:48
Data point term sent to Coder	System	14 Sep 2020 22:39:31
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition #9 HYPOTHYROIDISM (01 JUN 2003-ONGOING). If yes, please ensure only one entry is recorded. ' answered with 'Field was corrected' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:39:04
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:38:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:38:47
User entered 'Hot flashes' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:38:47
Data point term sent to Coder	System	14 Sep 2020 22:38:30
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:38:23
Data point term sent to Coder	System	14 Sep 2020 22:36:27
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:35:46
Data point term sent to Coder	System	14 Sep 2020 22:35:27
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:35:22
User entered empty; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:35:22

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition #9 HYPOTHYROIDISM (01 JUN 2003-ONGOING). If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:55:08
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid disorder, LLT: Thyroid disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:19:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:19:16
Data point term sent to Coder	System	10 Aug 2020 12:10:31
User entered 'Thyroid condition'	Tiffany Jewell (b) (4) (b) (4)	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 14:01:01
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	14 Sep 2020 22:38:47
User entered '1 Jan 2019' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:47
DataPoint activated with code reason code Data required.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	14 Sep 2020 22:35:22
User entered empty; reason for change Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:22
User entered '3 Jan 2003'	(b) (4) Tiffany Jewell (b) (4)	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:38:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:47
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User entered 'Yes (Y)'	System	14 Sep 2020 22:35:22
	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:22
	Tiffany Jewell (b) (4)	10 Aug 2020 12:09:37
	(b) (4)	

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	14 Sep 2020 22:38:47
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
	(b) (4)	
User entered empty.	System	14 Sep 2020 22:35:22
User entered 'Jan 2003'	System	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	14 Sep 2020 22:38:47
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
User entered empty.	System	14 Sep 2020 22:35:22
User entered '2003'	System	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
	(b) (4)	
User entered empty.	System	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
DataPoint activated with code reason code Data required.	Tiffany Jewell (b) (4)	14 Sep 2020 22:38:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Tiffany Jewell (b) (4)	14 Sep 2020 22:35:46
	(b) (4)	
User entered empty.	System	10 Aug 2020 12:09:37

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:24:42
Data point term sent to Coder	System	21 Oct 2020 19:23:53
Coding entries removed.	zackery harmon (b) (4)	21 Oct 2020 19:23:30
User entered 'Bilateral TUBAL LIGATION' reason for change: Data Entry Error	zackery harmon (b) (4)	21 Oct 2020 19:23:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:50:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:50:29
Data point term sent to Coder	System	19 Aug 2020 19:49:03
User entered 'Tubal Ligation'	Tiffany Jewell (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '3 Jan 2003'	Tiffany Jewell (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:24:36
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Field corrected' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:34:18
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:34:00
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:55:26
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '3 Jan 2003' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:34:00
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2003'	System	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2003'	System	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2003'	System	14 Sep 2020 22:34:00
User entered empty.	System	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2003'	System	14 Sep 2020 22:34:00
User entered empty.	System	19 Aug 2020 19:48:31

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:57:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:57:28
Data point term sent to Coder	System	19 Aug 2020 19:56:25
User entered 'Cesarean Section'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2001'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2001'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2001'	System	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2001'	System	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2001'	System	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2001'	System	19 Aug 2020 19:55:53

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 13:15:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 13:15:49
Data point term sent to Coder	System	19 Aug 2020 19:57:29
User entered 'Uterine Ablation- Irregular periods'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2016'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2016'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2016'	System	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2016'	System	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2016'	System	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2016'	System	19 Aug 2020 19:57:26

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Smear cervix abnormal, LLT: Pap smear abnormal - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 05:06:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 05:06:41
Data point term sent to Coder	System	19 Aug 2020 19:58:32
User entered 'Cold Knife Cone- Abnormal pap smear'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'UN UNK 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	19 Aug 2020 19:58:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Nervous system disorders, HLGT: Demyelinating disorders, HLT: Multiple sclerosis acute and progressive, PT: Multiple sclerosis, LLT: Multiple sclerosis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:00:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:00:23
Data point term sent to Coder	System	19 Aug 2020 19:59:34
User entered 'Multiple Sclerosis'	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Dec 2006'	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Dec 2006'	System	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2006'	System	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 19:59:14

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Insulin resistance, LLT: Insulin resistance - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:17:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:17:07
Data point term sent to Coder	System	19 Aug 2020 20:16:28
User entered 'Insulin Resistance'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Jun 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jun 2019'	System	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 20:16:01

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
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)	19 Aug 2020 20:18:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:18:25
Data point term sent to Coder	System	19 Aug 2020 20:17:32
User entered 'Hypothyroidism'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Jun 2003'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jun 2003'	System	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2003'	System	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	19 Aug 2020 20:16:31

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Per MM, please split and record the conditions separately as applicable' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:25:15
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:41:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:41:15
Data point term sent to Coder	System	06 Oct 2020 12:40:10
Query 'Per MM, please split and record the conditions separately as applicable' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	06 Oct 2020 12:40:08
Coding entries removed.	Tiffany Jewell (b) (4) (b) (4)	06 Oct 2020 12:39:58
User entered 'ANXIETY' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	06 Oct 2020 12:39:58
User opened query 'Per MM, please split and record the conditions separately as applicable' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:29:56
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Anxiety depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:41:49
Data point term sent to Coder	System	14 Sep 2020 22:40:34
User entered 'Anxiety/Depression'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Jan 2019'	Tiffany Jewell (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	14 Sep 2020 22:40:28

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 12:42:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 12:42:18
Data point term sent to Coder	System	06 Oct 2020 12:41:12
User entered 'Depression'	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '1 Jan 2019'	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	06 Oct 2020 12:40:35

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 15:19:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 15:19:24
Data point term sent to Coder	System	04 Nov 2020 14:17:08
User entered 'obesity (BMI- 33.5)'	Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	04 Nov 2020 14:16:57
User entered 'UN UNK 2019' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 14:16:57
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	04 Nov 2020 14:16:16
User entered '26 Oct 2020'	Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	(b) (4) Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	(b) (4) Teresa Deese (b) (4)	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'Jan 2019'	System	04 Nov 2020 14:16:57
User entered 'Oct 2020'	System	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '2019'	System	04 Nov 2020 14:16:57
User entered '2020'	System	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered empty.	System	04 Nov 2020 14:16:16

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '10:36'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered '8 Aug 2020 10:36'	System	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '153' cm	(b) (4) Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02
DataPoint set to visible.	(b) (4) System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '78.5' kg	(b) (4) Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02
DataPoint set to visible.	(b) (4) System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
Amendment Manager: User entered '33.53411'	System	16 Sep 2020 23:48:34
User entered '33.5'	System	10 Aug 2020 12:12:02
DataPoint set to visible.	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'kg/m2'	System	10 Aug 2020 12:12:02
DataPoint set to visible.	System	08 Aug 2020 15:09:44

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '37.1' C	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '68'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'bpm'	System	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'breaths/min'	System	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '110'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'mmHg'	System	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '80'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:02

US3202070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User entered 'mmHg'	System	10 Aug 2020 12:12:02

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:12:59

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:23:52
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:46:47
User entered '8 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	10 Aug 2020 12:12:59

US3202070

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

US3202070

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '3 Jan 2003'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:43:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:13:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:16:54
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 12:16:17
	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Claims Assistant'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

US3202070

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

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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)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

US3202070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'I'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

US3202070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '0'	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

US3202070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:55:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Tiffany Jewell (b) (4)	10 Aug 2020 12:16:17

US3202070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:07:19

US3202070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:07:19

US3202070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:07:19

US3202070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'VISIT1'	System	08 Aug 2020 15:07:19

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:20:27

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:03:59
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:03:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 14:20:27
User entered '102190' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:20:27

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:20:27

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:09:17

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:09:17

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:09:17

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:09:17

US3202070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:09:17

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:42
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:44
User entered '153' cm	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:45
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:50
User entered '78.5' kg	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:42
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:44
User entered '153' cm	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:45
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:50
User entered '78.5' kg	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '10:36'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '8 Aug 2020 10:36'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '37.1' C	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '68'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'bpm'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'breaths/min'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '110'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '80'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:42
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:44
User entered '153' cm	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:25:45
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:03:32
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:26:50
User entered '78.5' kg	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 19:53:22
User entered '11:45'	Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22
	(b) (4)	

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '8 Aug 2020 11:45'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '36.5' C	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '84'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'bpm'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'breaths/min'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '106'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '62'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	19 Aug 2020 19:53:22

US3202070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:59:34

US3202070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:59:34

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '11:03'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '08 Aug 2020 11:03'	System	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'ONCE'	System	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 15:10:20

US3202070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:17

US3202070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:17

US3202070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '10:43'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:17

US3202070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '8 Aug 2020 10:43'	System	25 Aug 2020 20:29:17

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '8 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '10:40'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '8 Aug 2020 10:40'	System	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered empty.	System	25 Aug 2020 20:29:35

US3202070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 19:59:41

US3202070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	19 Aug 2020 19:59:41

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:28:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '65fdc8e4-b8d9-4063-b7a0-261840f15809'	System	08 Aug 2020 15:31:07
User entered 'Yes (Y)'	System	08 Aug 2020 15:31:07

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:30:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '65fdc8e4-b8d9-4063-b7a0-261840f15809'	System	08 Aug 2020 15:31:07
User entered '97.9'	System	08 Aug 2020 15:31:07

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:30:59', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '65fdc8e4-b8d9-4063-b7a0-261840f15809'	System	08 Aug 2020 15:31:07
User entered 'No (N)'	System	08 Aug 2020 15:31:07

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:31:05', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '65fdc8e4-b8d9-4063-b7a0-261840f15809'	System	08 Aug 2020 15:31:07
User entered '08 Aug 2020 11:31'	System	08 Aug 2020 15:31:07

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 11:23'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 13:53'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:12:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ab785685-db37-484a-93b4-1beab4c7f49e'	System	08 Aug 2020 21:12:56
User entered 'Yes (Y)'	System	08 Aug 2020 21:12:56

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:12:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ab785685-db37-484a-93b4-1beab4c7f49e'	System	08 Aug 2020 21:12:56
User entered '98.2'	System	08 Aug 2020 21:12:56

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:12:48', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ab785685-db37-484a-93b4-1beab4c7f49e'	System	08 Aug 2020 21:12:56
User entered 'No (N)'	System	08 Aug 2020 21:12:56

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:12:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ab785685-db37-484a-93b4-1beab4c7f49e'	System	08 Aug 2020 21:12:56
User entered '08 Aug 2020 17:12'	System	08 Aug 2020 21:12:56

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 14:48'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 2'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:01:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '1c93d38f-901a-4a2e-842c-69e8057f25aa'	System	09 Aug 2020 16:01:58
User entered 'Yes (Y)'	System	09 Aug 2020 16:01:58

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:01:41', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '1c93d38f-901a-4a2e-842c-69e8057f25aa'	System	09 Aug 2020 16:01:58
User entered '97.5'	System	09 Aug 2020 16:01:58

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:01:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '1c93d38f-901a-4a2e-842c-69e8057f25aa'	System	09 Aug 2020 16:01:58
User entered 'No (N)'	System	09 Aug 2020 16:01:58

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:01:57', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '1c93d38f-901a-4a2e-842c-69e8057f25aa'	System	09 Aug 2020 16:01:58
User entered '09 Aug 2020 12:01'	System	09 Aug 2020 16:01:58

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 3'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:00:17', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2f6d99fa-b682-4c68-8112-603f773e98c1'	System	10 Aug 2020 23:00:35
User entered 'Yes (Y)'	System	10 Aug 2020 23:00:35

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:00:22', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2f6d99fa-b682-4c68-8112-603f773e98c1'	System	10 Aug 2020 23:00:35
User entered '98.0'	System	10 Aug 2020 23:00:35

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:00:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2f6d99fa-b682-4c68-8112-603f773e98c1'	System	10 Aug 2020 23:00:35
User entered 'No (N)'	System	10 Aug 2020 23:00:35

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:00:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2f6d99fa-b682-4c68-8112-603f773e98c1'	System	10 Aug 2020 23:00:35
User entered '10 Aug 2020 19:00'	System	10 Aug 2020 23:00:35

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 4'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:40:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088fd06c-c8f3-4948-9eb8-1cd5adf8328b'	System	12 Aug 2020 00:41:09
User entered 'Yes (Y)'	System	12 Aug 2020 00:41:09

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:40:57', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088fd06c-c8f3-4948-9eb8-1cd5adf8328b'	System	12 Aug 2020 00:41:09
User entered '99.2'	System	12 Aug 2020 00:41:09

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:01', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088fd06c-c8f3-4948-9eb8-1cd5adf8328b'	System	12 Aug 2020 00:41:09
User entered 'No (N)'	System	12 Aug 2020 00:41:09

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088fd06c-c8f3-4948-9eb8-1cd5adf8328b'	System	12 Aug 2020 00:41:09
User entered '11 Aug 2020 20:41'	System	12 Aug 2020 00:41:09

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 5'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:15:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a3b87632-0ee7-456e-b0dd-188bdd1f5daa'	System	12 Aug 2020 21:16:26
User entered 'Yes (Y)'	System	12 Aug 2020 21:16:26

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a3b87632-0ee7-456e-b0dd-188bdd1f5daa'	System	12 Aug 2020 21:16:26
User entered '98.5'	System	12 Aug 2020 21:16:26

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a3b87632-0ee7-456e-b0dd-188bdd1f5daa'	System	12 Aug 2020 21:16:26
User entered 'No (N)'	System	12 Aug 2020 21:16:26

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a3b87632-0ee7-456e-b0dd-188bdd1f5daa'	System	12 Aug 2020 21:16:26
User entered '12 Aug 2020 17:16'	System	12 Aug 2020 21:16:26

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 6'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	System	13 Aug 2020 21:11:47
User entered 'Yes (Y)'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	System	13 Aug 2020 21:11:47
User entered '98.7'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:23', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	System	13 Aug 2020 21:11:47
User entered 'Yes (Y)'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT DENIED MEDICATION TAKEN FOR VACCINE RELATED SYMPTOMS DURING F/UP PHONE CALL' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:39:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	Erica Osmundsen (b) (4)	25 Aug 2020 20:48:37
User entered '1'	System	13 Aug 2020 21:11:47
	System	13 Aug 2020 21:11:47
	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	System	13 Aug 2020 21:11:47
User entered '0'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c752040a-fa98-460c-8513-596bae7fcff3'	System	13 Aug 2020 21:11:47
User entered '13 Aug 2020 17:11'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 7'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:47:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	System	15 Aug 2020 04:48:21
User entered 'Yes (Y)'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:47:57', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	System	15 Aug 2020 04:48:21
User entered '96.8'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	System	15 Aug 2020 04:48:21
User entered 'Yes (Y)'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT DENIED ANY ADDITIONAL MEDICATIONS TAKEN' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:40:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	Erica Osmundsen (b) (4)	25 Aug 2020 20:49:08
User entered '1'	System	15 Aug 2020 04:48:21
	System	15 Aug 2020 04:48:21
	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	System	15 Aug 2020 04:48:21
User entered '0'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'df73091c-5b8f-44a2-b089-77c3f1c75bc0'	System	15 Aug 2020 04:48:21
User entered '15 Aug 2020 00:48'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	13 Aug 2020 21:11:47
User entered 'Day 8'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	15 Aug 2020 04:48:21
User entered 'Day 9'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:04:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b6cf2fcd-906e-4587-9e84-cdae48085e'	System	17 Aug 2020 05:04:55
User entered 'Yes (Y)'	System	17 Aug 2020 05:04:55

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:04:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b6cf2fcd-906e-4587-9e84-cdae48085e'	System	17 Aug 2020 05:04:55
User entered '97.4'	System	17 Aug 2020 05:04:55

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:04:46', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b6cf2fcd-906e-4587-9e84-cdae8a48085e'	System	17 Aug 2020 05:04:55
User entered 'No (N)'	System	17 Aug 2020 05:04:55

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:04:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b6cf2fcd-906e-4587-9e84-cdaeba48085e'	System	17 Aug 2020 05:04:55
User entered '17 Aug 2020 01:04'	System	17 Aug 2020 05:04:55

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:31:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '502078f2-f91e-4cf9-87a5-ed76547e996d'	System	08 Aug 2020 15:32:40
User entered 'None (1)'	System	08 Aug 2020 15:32:40

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:32:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '502078f2-f91e-4cf9-87a5-ed76547e996d'	System	08 Aug 2020 15:32:40
User entered 'No (N)'	System	08 Aug 2020 15:32:40

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:32:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '502078f2-f91e-4cf9-87a5-ed76547e996d'	System	08 Aug 2020 15:32:40
User entered 'No (N)'	System	08 Aug 2020 15:32:40

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:32:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '502078f2-f91e-4cf9-87a5-ed76547e996d'	System	08 Aug 2020 15:32:40
User entered 'None (1)'	System	08 Aug 2020 15:32:40

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:32:34', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '502078f2-f91e-4cf9-87a5-ed76547e996d'	System	08 Aug 2020 15:32:40
User entered '08 Aug 2020 11:32'	System	08 Aug 2020 15:32:40

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 11:23'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 13:53'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:08', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd2bcd02a-7fda-4fa7-a9db-3ed0f15ec319'	System	08 Aug 2020 21:13:38
User entered 'None (1)'	System	08 Aug 2020 21:13:38

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:17', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd2bcd02a-7fda-4fa7-a9db-3ed0f15ec319'	System	08 Aug 2020 21:13:38
User entered 'No (N)'	System	08 Aug 2020 21:13:38

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd2bcd02a-7fda-4fa7-a9db-3ed0f15ec319'	System	08 Aug 2020 21:13:38
User entered 'No (N)'	System	08 Aug 2020 21:13:38

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd2bcd02a-7fda-4fa7-a9db-3ed0f15ec319'	System	08 Aug 2020 21:13:38
User entered 'None (1)'	System	08 Aug 2020 21:13:38

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd2bcd02a-7fda-4fa7-a9db-3ed0f15ec319'	System	08 Aug 2020 21:13:38
User entered '08 Aug 2020 17:13'	System	08 Aug 2020 21:13:38

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 14:48'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 2'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '0b05ae53-fe5b-46e0-9de7-089e6a814ecd'	System	09 Aug 2020 16:02:35
User entered 'None (1)'	System	09 Aug 2020 16:02:35

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:16', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '0b05ae53-fe5b-46e0-9de7-089e6a814ecd'	System	09 Aug 2020 16:02:35
User entered 'No (N)'	System	09 Aug 2020 16:02:35

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '0b05ae53-fe5b-46e0-9de7-089e6a814ecd'	System	09 Aug 2020 16:02:35
User entered 'No (N)'	System	09 Aug 2020 16:02:35

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '0b05ae53-fe5b-46e0-9de7-089e6a814ecd'	System	09 Aug 2020 16:02:35
User entered 'None (1)'	System	09 Aug 2020 16:02:35

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '0b05ae53-fe5b-46e0-9de7-089e6a814ecd'	System	09 Aug 2020 16:02:35
User entered '09 Aug 2020 12:02'	System	09 Aug 2020 16:02:35

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 3'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:00:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '3755aff2-6f58-4843-bc4a-39b19de04563'	System	10 Aug 2020 23:01:44
User entered 'None (1)'	System	10 Aug 2020 23:01:44

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '3755aff2-6f58-4843-bc4a-39b19de04563'	System	10 Aug 2020 23:01:44
User entered 'No (N)'	System	10 Aug 2020 23:01:44

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '3755aff2-6f58-4843-bc4a-39b19de04563'	System	10 Aug 2020 23:01:44
User entered 'No (N)'	System	10 Aug 2020 23:01:44

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '3755aff2-6f58-4843-bc4a-39b19de04563'	System	10 Aug 2020 23:01:44
User entered 'None (1)'	System	10 Aug 2020 23:01:44

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '3755aff2-6f58-4843-bc4a-39b19de04563'	System	10 Aug 2020 23:01:44
User entered '10 Aug 2020 19:01'	System	10 Aug 2020 23:01:44

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 4'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:08', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '104d0117-8ffc-4ce9-b03a-189165e00bff'	System	12 Aug 2020 00:41:24
User entered 'None (1)'	System	12 Aug 2020 00:41:24

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '104d0117-8ffc-4ce9-b03a-189165e00bff'	System	12 Aug 2020 00:41:24
User entered 'No (N)'	System	12 Aug 2020 00:41:24

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:14', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '104d0117-8ffc-4ce9-b03a-189165e00bff'	System	12 Aug 2020 00:41:24
User entered 'No (N)'	System	12 Aug 2020 00:41:24

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:18', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '104d0117-8ffc-4ce9-b03a-189165e00bff'	System	12 Aug 2020 00:41:24
User entered 'None (1)'	System	12 Aug 2020 00:41:24

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:21', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '104d0117-8ffc-4ce9-b03a-189165e00bff'	System	12 Aug 2020 00:41:24
User entered '11 Aug 2020 20:41'	System	12 Aug 2020 00:41:24

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 5'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:24', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'fc298733-0229-400e-b28f-682fd0f47c2b'	System	12 Aug 2020 21:16:37
User entered 'None (1)'	System	12 Aug 2020 21:16:37

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:26', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'fc298733-0229-400e-b28f-682fd0f47c2b'	System	12 Aug 2020 21:16:37
User entered 'No (N)'	System	12 Aug 2020 21:16:37

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'fc298733-0229-400e-b28f-682fd0f47c2b'	System	12 Aug 2020 21:16:37
User entered 'No (N)'	System	12 Aug 2020 21:16:37

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'fc298733-0229-400e-b28f-682fd0f47c2b'	System	12 Aug 2020 21:16:37
User entered 'None (1)'	System	12 Aug 2020 21:16:37

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'fc298733-0229-400e-b28f-682fd0f47c2b'	System	12 Aug 2020 21:16:37
User entered '12 Aug 2020 17:16'	System	12 Aug 2020 21:16:37

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 6'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:46', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c578029a-ce3c-4c0c-bf1e-2f07c153a2d5'	System	13 Aug 2020 21:12:04
User entered 'None (1)'	System	13 Aug 2020 21:12:04

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c578029a-ce3c-4c0c-bf1e-2f07c153a2d5'	System	13 Aug 2020 21:12:04
User entered 'No (N)'	System	13 Aug 2020 21:12:04

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c578029a-ce3c-4c0c-bf1e-2f07c153a2d5'	System	13 Aug 2020 21:12:04
User entered 'No (N)'	System	13 Aug 2020 21:12:04

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c578029a-ce3c-4c0c-bf1e-2f07c153a2d5'	System	13 Aug 2020 21:12:04
User entered 'None (1)'	System	13 Aug 2020 21:12:04

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:11:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c578029a-ce3c-4c0c-bf1e-2f07c153a2d5'	System	13 Aug 2020 21:12:04
User entered '13 Aug 2020 17:11'	System	13 Aug 2020 21:12:04

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 7'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f340f867-34ae-4a5c-a477-b3521e312c36'	System	15 Aug 2020 04:48:41
User entered 'None (1)'	System	15 Aug 2020 04:48:41

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f340f867-34ae-4a5c-a477-b3521e312c36'	System	15 Aug 2020 04:48:41
User entered 'No (N)'	System	15 Aug 2020 04:48:41

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f340f867-34ae-4a5c-a477-b3521e312c36'	System	15 Aug 2020 04:48:41
User entered 'No (N)'	System	15 Aug 2020 04:48:41

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f340f867-34ae-4a5c-a477-b3521e312c36'	System	15 Aug 2020 04:48:41
User entered 'None (1)'	System	15 Aug 2020 04:48:41

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f340f867-34ae-4a5c-a477-b3521e312c36'	System	15 Aug 2020 04:48:41
User entered '15 Aug 2020 00:48'	System	15 Aug 2020 04:48:41

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:37:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'No interference with activity (1)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:37:48', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'None (0)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:37:51', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'None (0)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:37:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'None (0)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:37:59', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'None (0)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:38:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'None (0)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:38:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered 'No (N)'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T11:39:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '90d5a182-bd4e-4773-93bb-2d68e391a0c5'	System	08 Aug 2020 15:39:06
User entered '08 Aug 2020 11:39'	System	08 Aug 2020 15:39:06

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 11:23'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 13:53'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'None (0)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'No interference with activity (1)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'None (0)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'None (0)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:13:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'None (0)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:14:01', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'None (0)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:14:07', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered 'No (N)'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-08T17:14:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'd54dffcc-2085-4342-bf65-62dd1c0396c9'	System	08 Aug 2020 21:14:15
User entered '08 Aug 2020 17:14'	System	08 Aug 2020 21:14:15

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '08 Aug 2020 14:48'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 2'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:38', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'None (0)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:41', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'No interference with activity (1)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:44', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'None (0)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'None (0)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'None (0)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'None (0)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered 'No (N)'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-09T12:02:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '51223e6d-e500-4f20-ba0f-b49da5715762'	System	09 Aug 2020 16:03:01
User entered '09 Aug 2020 12:02'	System	09 Aug 2020 16:03:01

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 3'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:46', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'None (0)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:51', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'None (0)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'None (0)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'None (0)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:01:59', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'None (0)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:02:03', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered 'No (N)'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-10T19:02:06', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6732133d-53f7-4a8f-ad38-750113b0755c'	System	10 Aug 2020 23:02:09
User entered '10 Aug 2020 19:02'	System	10 Aug 2020 23:02:09

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 4'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'None (0)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered 'No (N)'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-11T20:41:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6ab359f2-dd35-419d-84ac-9baa3cbd5b9c'	System	12 Aug 2020 00:41:42
User entered '11 Aug 2020 20:41'	System	12 Aug 2020 00:41:42

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 5'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'Some interference with activity (2)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:48', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'None (0)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'None (0)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:16:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'None (0)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:17:01', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered 'No (N)'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-12T17:17:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '738c982a-d80d-47fc-94f0-bb2a36a169ed'	System	12 Aug 2020 21:17:08
User entered '12 Aug 2020 17:17'	System	12 Aug 2020 21:17:08

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 6'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'No interference with activity (1)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:16', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'No interference with activity (1)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:18', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'None (0)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'None (0)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:22', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'None (0)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:24', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'None (0)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered 'No (N)'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-13T17:12:30', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '81454d42-eb47-4648-a4bf-3451ea416851'	System	13 Aug 2020 21:12:34
User entered '13 Aug 2020 17:12'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 7'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:44', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'No interference with activity (1)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'No interference with activity (1)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'None (0)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'None (0)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'None (0)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:48:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'None (0)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:49:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered 'No (N)'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-15T00:49:07', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '26ea3c8f-01cf-4bcc-8bea-0b70c867899d'	System	15 Aug 2020 04:49:10
User entered '15 Aug 2020 00:49'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	13 Aug 2020 21:12:34
User entered 'Day 8'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	15 Aug 2020 04:49:10
User entered 'Day 9'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '23b317fb-f577-46bb-8ea2-e132f9920fe7'	System	17 Aug 2020 05:05:18
User entered 'None (0)'	System	17 Aug 2020 05:05:18

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:13', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '23b317fb-f577-46bb-8ea2-e132f9920fe7'	System	17 Aug 2020 05:05:18
User entered '17 Aug 2020 01:05'	System	17 Aug 2020 05:05:18

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	13 Aug 2020 21:12:34
User entered 'Day 8'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:12:34

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	15 Aug 2020 04:49:10
User entered 'Day 9'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088efc45-a52a-40eb-9931-c376c1b98a60'	System	17 Aug 2020 05:05:25
User entered 'No interference with activity (1)'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:22', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '088efc45-a52a-40eb-9931-c376c1b98a60'	System	17 Aug 2020 05:05:25
User entered '17 Aug 2020 01:05'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 04:49:10

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	17 Aug 2020 05:05:25
User entered 'Day 10'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T07:25:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5834d62c-96a3-4cb6-b2f8-e062eaf61395'	System	18 Aug 2020 11:25:53
User entered 'No interference with activity (1)'	System	18 Aug 2020 11:25:53

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T07:25:48', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5834d62c-96a3-4cb6-b2f8-e062eaf61395'	System	18 Aug 2020 11:25:53
User entered '18 Aug 2020 07:25'	System	18 Aug 2020 11:25:53

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 12:00'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	17 Aug 2020 05:05:25
User entered 'Day 11'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T12:02:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'aa541ea4-7fec-49b4-98a5-fca4f9919442'	System	18 Aug 2020 16:02:22
User entered 'None (0)'	System	18 Aug 2020 16:02:22

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T12:02:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'aa541ea4-7fec-49b4-98a5-fca4f9919442'	System	18 Aug 2020 16:02:22
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 16:02:22

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	13 Aug 2020 21:11:47
User entered 'Day 8'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:11:47

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	15 Aug 2020 04:48:21
User entered 'Day 9'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '83b8216d-670b-43a4-83c6-ce18fe232a8f'	System	17 Aug 2020 05:05:34
User entered 'No (N)'	System	17 Aug 2020 05:05:34

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-17T01:05:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '83b8216d-670b-43a4-83c6-ce18fe232a8f'	System	17 Aug 2020 05:05:34
User entered '17 Aug 2020 01:05'	System	17 Aug 2020 05:05:34

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 04:48:21

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	17 Aug 2020 05:05:25
User entered 'Day 10'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T07:25:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '07abffd2-51e8-4917-ae77-1e308e57f94f'	System	18 Aug 2020 11:26:00
User entered 'No (N)'	System	18 Aug 2020 11:26:00

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T07:25:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '07abffd2-51e8-4917-ae77-1e308e57f94f'	System	18 Aug 2020 11:26:00
User entered '18 Aug 2020 07:25'	System	18 Aug 2020 11:26:00

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Aug 2020 12:00'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	17 Aug 2020 05:05:25
User entered 'Day 11'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T12:02:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4ead592b-827e-4c94-8a5a-df93cfc5d746'	System	18 Aug 2020 16:02:25
User entered 'No (N)'	System	18 Aug 2020 16:02:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3f3f283f18a7e7cf)', Time: '2020-08-18T12:02:18', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4ead592b-827e-4c94-8a5a-df93cfc5d746'	System	18 Aug 2020 16:02:25
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 16:02:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 05:05:25

US3202070

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 05:05:25

US3202070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 20:26:19

US3202070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 11:29:16
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'yes, due to business hours' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 20:26:40
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 20:26:19
User entered '19 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 20:26:19

US3202070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 20:26:19

US3202070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Lilian Nukuna (b) (4)	19 Aug 2020 20:26:19

US3202070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 20:00:34

US3202070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	19 Aug 2020 20:00:34

US3202070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:42:48

US3202070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:58
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 'The date is correct ' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:44:15
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 22:42:48
User entered '26 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:42:48

US3202070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:42:48

US3202070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No answer'	Tiffany Jewell (b) (4)	14 Sep 2020 22:42:48

US3202070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:46:32

US3202070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	14 Sep 2020 21:46:32

US3202070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:44:36

US3202070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:46:15
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'The date is correct ' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:44:40
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 22:44:36
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:44:36

US3202070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:44:36

US3202070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No answer'	Tiffany Jewell (b) (4)	14 Sep 2020 22:44:36

US3202070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:46:37

US3202070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	14 Sep 2020 21:46:37

US3202070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:46:47

US3202070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:31:54
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:31:52
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' answered with 'not an AE scheduling issues between pt and site' (Site from DM).	zackery harmon (b) (4) (b) (4)	27 Sep 2020 12:35:33
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:27:08
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		16 Sep 2020 23:48:34
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'The date is correct' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 21:46:56
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 21:46:47
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 21:46:47

US3202070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:46:47

US3202070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'VISIT2'	System	14 Sep 2020 21:46:47

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16:28'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '14 Sep 2020 16:28'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '36.6' C	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '54'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'bpm'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'breaths/min'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '108'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '72'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '18:01'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '14 Sep 2020 18:01'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '36.8' C	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '58'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'bpm'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 22:47:23
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	14 Sep 2020 22:47:23
User entered '14' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 22:47:23
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 22:47:04
User entered '58'	Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'breaths/min'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '106'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '70'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	14 Sep 2020 22:47:04

US3202070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:09

US3202070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:09

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '17:22' reason for change: Data Entry Error	(b) (4)	
	Tiffany Jewell (b) (4)	14 Sep 2020 21:59:01
User entered '17:52'	(b) (4)	
	Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33
	(b) (4)	

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '14 Sep 2020 17:22'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 17:52'	System	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'ONCE'	System	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 21:47:33

US3202070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:52

US3202070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:52

US3202070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '17:03'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:47:52

US3202070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '14 Sep 2020 17:03'	System	14 Sep 2020 21:47:52

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16:59'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '14 Sep 2020 16:59'	System	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered empty.	System	14 Sep 2020 21:48:15

US3202070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 21:48:20

US3202070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '1'	System	14 Sep 2020 21:48:20

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:05:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7d3d5d32-48d5-4d45-b626-3134a939e1e2'	System	14 Sep 2020 22:05:56
User entered 'Yes (Y)'	System	14 Sep 2020 22:05:56

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T18:05:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7d3d5d32-48d5-4d45-b626-3134a939e1e2'	System	14 Sep 2020 22:05:56
User entered '98.3'	System	14 Sep 2020 22:05:56

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:05:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7d3d5d32-48d5-4d45-b626-3134a939e1e2'	System	14 Sep 2020 22:05:56
User entered 'No (N)'	System	14 Sep 2020 22:05:56

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T18:05:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7d3d5d32-48d5-4d45-b626-3134a939e1e2'	System	14 Sep 2020 22:05:56
User entered '14 Sep 2020 18:05'	System	14 Sep 2020 22:05:56

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 18:12'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 20:12'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 20:42'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:30:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '43e2fd5d-a09b-4d00-88a5-65ae6be2e095'	System	15 Sep 2020 01:31:44
User entered 'Yes (Y)'	System	15 Sep 2020 01:31:44

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:17', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '43e2fd5d-a09b-4d00-88a5-65ae6be2e095'	System	15 Sep 2020 01:31:44
User entered '98.1'	System	15 Sep 2020 01:31:44

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '43e2fd5d-a09b-4d00-88a5-65ae6be2e095'	System	15 Sep 2020 01:31:44
User entered 'No (N)'	System	15 Sep 2020 01:31:44

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '43e2fd5d-a09b-4d00-88a5-65ae6be2e095'	System	15 Sep 2020 01:31:44
User entered '14 Sep 2020 21:31'	System	15 Sep 2020 01:31:44

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 21:07'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 21:37'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 2'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:05:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e9bac17a-a270-4e09-8b1e-285a10692d3f'	System	16 Sep 2020 10:06:22
User entered 'Yes (Y)'	System	16 Sep 2020 10:06:22

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e9bac17a-a270-4e09-8b1e-285a10692d3f' User entered '97.4'	System	16 Sep 2020 10:06:22
	System	16 Sep 2020 10:06:22

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e9bac17a-a270-4e09-8b1e-285a10692d3f'	System	16 Sep 2020 10:06:22
User entered 'No (N)'	System	16 Sep 2020 10:06:22

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e9bac17a-a270-4e09-8b1e-285a10692d3f'	System	16 Sep 2020 10:06:22
User entered '16 Sep 2020 06:06'	System	16 Sep 2020 10:06:22

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 3'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '055ae013-4960-49cb-a949-3caa005d2837'	System	17 Sep 2020 11:21:32
User entered 'Yes (Y)'	System	17 Sep 2020 11:21:32

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:23', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '055ae013-4960-49cb-a949-3caa005d2837'	System	17 Sep 2020 11:21:32
User entered '98.7'	System	17 Sep 2020 11:21:32

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '055ae013-4960-49cb-a949-3caa005d2837'	System	17 Sep 2020 11:21:32
User entered 'No (N)'	System	17 Sep 2020 11:21:32

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '055ae013-4960-49cb-a949-3caa005d2837'	System	17 Sep 2020 11:21:32
User entered '17 Sep 2020 07:21'	System	17 Sep 2020 11:21:32

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 4'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-18T06:56:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5efc2bd1-ddf9-4f90-9873-89c6a35a9b8b'	System	18 Sep 2020 10:58:31
User entered 'Yes (Y)'	System	18 Sep 2020 10:58:31

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-18T06:58:22', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5efc2bd1-ddf9-4f90-9873-89c6a35a9b8b'	System	18 Sep 2020 10:58:31
User entered '97.8'	System	18 Sep 2020 10:58:31

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-18T06:58:24', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5efc2bd1-ddf9-4f90-9873-89c6a35a9b8b'	System	18 Sep 2020 10:58:31
User entered 'No (N)'	System	18 Sep 2020 10:58:31

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-18T06:58:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5efc2bd1-ddf9-4f90-9873-89c6a35a9b8b'	System	18 Sep 2020 10:58:31
User entered '18 Sep 2020 06:58'	System	18 Sep 2020 10:58:31

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 5'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-19T11:53:41', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a9b75dae-c627-4948-b13c-9dd1d3cf1856'	System	19 Sep 2020 15:55:15
User entered 'Yes (Y)'	System	19 Sep 2020 15:55:15

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-19T11:55:06', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a9b75dae-c627-4948-b13c-9dd1d3cf1856'	System	19 Sep 2020 15:55:15
User entered '98.2'	System	19 Sep 2020 15:55:15

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-19T11:55:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a9b75dae-c627-4948-b13c-9dd1d3cf1856'	System	19 Sep 2020 15:55:15
User entered 'No (N)'	System	19 Sep 2020 15:55:15

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-19T11:55:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a9b75dae-c627-4948-b13c-9dd1d3cf1856'	System	19 Sep 2020 15:55:15
User entered '19 Sep 2020 11:55'	System	19 Sep 2020 15:55:15

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 6'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-20T09:08:21', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '9a4d99b1-182e-48e9-af4d-ba331f27d781'	System	20 Sep 2020 13:10:01
User entered 'Yes (Y)'	System	20 Sep 2020 13:10:01

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-20T09:09:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '9a4d99b1-182e-48e9-af4d-ba331f27d781'	System	20 Sep 2020 13:10:01
User entered '97.6'	System	20 Sep 2020 13:10:01

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-20T09:09:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '9a4d99b1-182e-48e9-af4d-ba331f27d781'	System	20 Sep 2020 13:10:01
User entered 'No (N)'	System	20 Sep 2020 13:10:01

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:09:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '9a4d99b1-182e-48e9-af4d-ba331f27d781'	System	20 Sep 2020 13:10:01
User entered '20 Sep 2020 09:09'	System	20 Sep 2020 13:10:01

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 7'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:38:17', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '78e83c0a-65d1-40ed-9422-f2dd0f871920'	System	21 Sep 2020 10:39:43
User entered 'Yes (Y)'	System	21 Sep 2020 10:39:43

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:39:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '78e83c0a-65d1-40ed-9422-f2dd0f871920'	System	21 Sep 2020 10:39:43
User entered '97.5'	System	21 Sep 2020 10:39:43

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-21T06:39:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '78e83c0a-65d1-40ed-9422-f2dd0f871920'	System	21 Sep 2020 10:39:43
User entered 'No (N)'	System	21 Sep 2020 10:39:43

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:39:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '78e83c0a-65d1-40ed-9422-f2dd0f871920'	System	21 Sep 2020 10:39:43
User entered '21 Sep 2020 06:39'	System	21 Sep 2020 10:39:43

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:03', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c1097616-33d4-4b92-8f38-78428be7e728'	System	14 Sep 2020 22:06:20
User entered 'None (1)'	System	14 Sep 2020 22:06:20

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T18:06:06', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c1097616-33d4-4b92-8f38-78428be7e728'	System	14 Sep 2020 22:06:20
User entered 'No (N)'	System	14 Sep 2020 22:06:20

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T18:06:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c1097616-33d4-4b92-8f38-78428be7e728'	System	14 Sep 2020 22:06:20
User entered 'No (N)'	System	14 Sep 2020 22:06:20

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:13', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c1097616-33d4-4b92-8f38-78428be7e728'	System	14 Sep 2020 22:06:20
User entered 'None (1)'	System	14 Sep 2020 22:06:20

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:16', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c1097616-33d4-4b92-8f38-78428be7e728'	System	14 Sep 2020 22:06:20
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 22:06:20

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 18:12'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 20:12'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 20:42'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:46', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c39c6250-6566-4ecd-b503-9dc838049fe5'	System	15 Sep 2020 01:32:04
User entered 'None (1)'	System	15 Sep 2020 01:32:04

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c39c6250-6566-4ecd-b503-9dc838049fe5'	System	15 Sep 2020 01:32:04
User entered 'No (N)'	System	15 Sep 2020 01:32:04

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c39c6250-6566-4ecd-b503-9dc838049fe5'	System	15 Sep 2020 01:32:04
User entered 'No (N)'	System	15 Sep 2020 01:32:04

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c39c6250-6566-4ecd-b503-9dc838049fe5'	System	15 Sep 2020 01:32:04
User entered 'None (1)'	System	15 Sep 2020 01:32:04

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:31:59', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c39c6250-6566-4ecd-b503-9dc838049fe5'	System	15 Sep 2020 01:32:04
User entered '14 Sep 2020 21:31'	System	15 Sep 2020 01:32:04

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 21:07'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 21:37'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 2'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '18482b7d-a711-4cd8-9aff-94fa2ebc833e'	System	16 Sep 2020 10:06:45
User entered 'None (1)'	System	16 Sep 2020 10:06:45

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '18482b7d-a711-4cd8-9aff-94fa2ebc833e'	System	16 Sep 2020 10:06:45
User entered 'No (N)'	System	16 Sep 2020 10:06:45

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:34', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '18482b7d-a711-4cd8-9aff-94fa2ebc833e'	System	16 Sep 2020 10:06:45
User entered 'No (N)'	System	16 Sep 2020 10:06:45

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '18482b7d-a711-4cd8-9aff-94fa2ebc833e'	System	16 Sep 2020 10:06:45
User entered 'None (1)'	System	16 Sep 2020 10:06:45

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '18482b7d-a711-4cd8-9aff-94fa2ebc833e'	System	16 Sep 2020 10:06:45
User entered '16 Sep 2020 06:06'	System	16 Sep 2020 10:06:45

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 3'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '995c35b2-4f80-4e03-ab38-0faeaa8dfa93'	System	17 Sep 2020 11:21:59
User entered 'None (1)'	System	17 Sep 2020 11:21:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '995c35b2-4f80-4e03-ab38-0faeaa8dfa93'	System	17 Sep 2020 11:21:59
User entered 'No (N)'	System	17 Sep 2020 11:21:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-17T07:21:49', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '995c35b2-4f80-4e03-ab38-0faeaa8dfa93'	System	17 Sep 2020 11:21:59
User entered 'No (N)'	System	17 Sep 2020 11:21:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '995c35b2-4f80-4e03-ab38-0faeaa8dfa93'	System	17 Sep 2020 11:21:59
User entered 'None (1)'	System	17 Sep 2020 11:21:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-17T07:21:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '995c35b2-4f80-4e03-ab38-0faeaa8dfa93'	System	17 Sep 2020 11:21:59
User entered '17 Sep 2020 07:21'	System	17 Sep 2020 11:21:59

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 4'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f3946c5a-4978-432e-8664-d91a15efc132'	System	18 Sep 2020 11:10:53
User entered 'None (1)'	System	18 Sep 2020 11:10:53

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f3946c5a-4978-432e-8664-d91a15efc132'	System	18 Sep 2020 11:10:53
User entered 'No (N)'	System	18 Sep 2020 11:10:53

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:43', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f3946c5a-4978-432e-8664-d91a15efc132'	System	18 Sep 2020 11:10:53
User entered 'No (N)'	System	18 Sep 2020 11:10:53

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f3946c5a-4978-432e-8664-d91a15efc132'	System	18 Sep 2020 11:10:53
User entered 'None (1)'	System	18 Sep 2020 11:10:53

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-18T07:10:48', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'f3946c5a-4978-432e-8664-d91a15efc132'	System	18 Sep 2020 11:10:53
User entered '18 Sep 2020 07:10'	System	18 Sep 2020 11:10:53

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 5'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '82e6ace5-9ca8-4699-b288-938bd8169cfd'	System	19 Sep 2020 15:55:26
User entered 'None (1)'	System	19 Sep 2020 15:55:26

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:17', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '82e6ace5-9ca8-4699-b288-938bd8169cfd'	System	19 Sep 2020 15:55:26
User entered 'No (N)'	System	19 Sep 2020 15:55:26

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-19T11:55:18', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '82e6ace5-9ca8-4699-b288-938bd8169cfd'	System	19 Sep 2020 15:55:26
User entered 'No (N)'	System	19 Sep 2020 15:55:26

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '82e6ace5-9ca8-4699-b288-938bd8169cfd'	System	19 Sep 2020 15:55:26
User entered 'None (1)'	System	19 Sep 2020 15:55:26

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-19T11:55:22', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '82e6ace5-9ca8-4699-b288-938bd8169cfd'	System	19 Sep 2020 15:55:26
User entered '19 Sep 2020 11:55'	System	19 Sep 2020 15:55:26

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 6'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8d54e39f-677a-4397-bb55-620daf8b3a9a'	System	20 Sep 2020 13:10:22
User entered 'None (1)'	System	20 Sep 2020 13:10:22

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8d54e39f-677a-4397-bb55-620daf8b3a9a'	System	20 Sep 2020 13:10:22
User entered 'No (N)'	System	20 Sep 2020 13:10:22

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8d54e39f-677a-4397-bb55-620daf8b3a9a'	System	20 Sep 2020 13:10:22
User entered 'No (N)'	System	20 Sep 2020 13:10:22

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8d54e39f-677a-4397-bb55-620daf8b3a9a'	System	20 Sep 2020 13:10:22
User entered 'None (1)'	System	20 Sep 2020 13:10:22

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8d54e39f-677a-4397-bb55-620daf8b3a9a'	System	20 Sep 2020 13:10:22
User entered '20 Sep 2020 09:10'	System	20 Sep 2020 13:10:22

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 7'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:39:44', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '163da1aa-3974-4fc5-b88d-a244d3420653'	System	21 Sep 2020 10:40:25
User entered 'None (1)'	System	21 Sep 2020 10:40:25

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-21T06:39:51', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '163da1aa-3974-4fc5-b88d-a244d3420653'	System	21 Sep 2020 10:40:25
User entered 'No (N)'	System	21 Sep 2020 10:40:25

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-21T06:40:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '163da1aa-3974-4fc5-b88d-a244d3420653'	System	21 Sep 2020 10:40:25
User entered 'No (N)'	System	21 Sep 2020 10:40:25

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:18', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '163da1aa-3974-4fc5-b88d-a244d3420653'	System	21 Sep 2020 10:40:25
User entered 'None (1)'	System	21 Sep 2020 10:40:25

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-21T06:40:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '163da1aa-3974-4fc5-b88d-a244d3420653'	System	21 Sep 2020 10:40:25
User entered '21 Sep 2020 06:40'	System	21 Sep 2020 10:40:25

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-14T18:06:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:34', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:38', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'None (0)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T18:06:41', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered 'No (N)'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T18:06:44', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c07bfa2d-d5da-4c81-9548-474afa6df721'	System	14 Sep 2020 22:06:48
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 22:06:48

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 18:12'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 20:12'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 20:42'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:32:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T21:32:07', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-14T21:32:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T21:32:12', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-14T21:32:14', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-14T21:32:16', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'None (0)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-14T21:32:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered 'No (N)'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-14T21:32:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4f1a9e7d-cafa-43dd-bba2-c4b3aec42db9'	System	15 Sep 2020 01:32:30
User entered '14 Sep 2020 21:32'	System	15 Sep 2020 01:32:30

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '14 Sep 2020 21:07'	System	14 Sep 2020 21:59:01
User entered '14 Sep 2020 21:37'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 2'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:45', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:50', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-16T06:06:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:06:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-16T06:06:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'None (0)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-16T06:06:59', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered 'No (N)'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-16T06:07:01', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '5c1e648f-09eb-483d-81a0-7d6d019e0ab2'	System	16 Sep 2020 10:07:07
User entered '16 Sep 2020 06:07'	System	16 Sep 2020 10:07:07

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 3'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:21:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:05', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:07', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'None (0)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:09', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered 'No (N)'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-17T07:22:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '38f37b13-6e0b-479b-b04f-6c1aed64d70c'	System	17 Sep 2020 11:22:15
User entered '17 Sep 2020 07:22'	System	17 Sep 2020 11:22:15

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 4'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:51', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:52', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-18T07:10:54', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:10:58', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:11:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'None (0)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:11:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered 'No (N)'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-18T07:11:05', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3d26d41-3ce7-45a6-bc6b-30dcbef50906'	System	18 Sep 2020 11:11:08
User entered '18 Sep 2020 07:11'	System	18 Sep 2020 11:11:08

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 5'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:26', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2020-09-19T11:55:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'None (0)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered 'No (N)'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-19T11:55:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '233a7b78-e694-4bc8-b6e3-f2b2a5eeede7'	System	19 Sep 2020 15:55:42
User entered '19 Sep 2020 11:55'	System	19 Sep 2020 15:55:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 6'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-20T09:10:23', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:26', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:31', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2020-09-20T09:10:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'None (0)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered 'No (N)'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-20T09:10:38', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ea5a2b71-aae8-42a3-aab9-a28d666859d8'	System	20 Sep 2020 13:10:42
User entered '20 Sep 2020 09:10'	System	20 Sep 2020 13:10:42

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	14 Sep 2020 21:47:33
User entered 'Day 7'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:23', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:25', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:27', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:30', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:32', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:34', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'None (0)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered 'No (N)'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-09-21T06:40:38', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c424b5df-67d9-43e5-891d-44e44fc78428'	System	21 Sep 2020 10:40:41
User entered '21 Sep 2020 06:40'	System	21 Sep 2020 10:40:41

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:47:33

US3202070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:47:33

US3202070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 18:14:54

US3202070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '21 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 18:14:54

US3202070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 18:14:54

US3202070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Lilian Nukuna (b) (4)	21 Sep 2020 18:14:54

US3202070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 18:15:00

US3202070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	21 Sep 2020 18:15:00

US3202070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:12:49

US3202070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '28 Sep 2020'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 20:12:49

US3202070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:12:49

US3202070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	Lilian Nukuna (b) (4)	28 Sep 2020 20:12:49

US3202070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:12:58

US3202070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	28 Sep 2020 20:12:58

US3202070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:04

US3202070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:04

US3202070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:04

US3202070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:04

US3202070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:10

US3202070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	13 Oct 2020 13:07:10

US3202070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:35

US3202070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:35

US3202070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:07:35

US3202070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'VISIT3'	System	13 Oct 2020 13:07:35

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16:12'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '12 Oct 2020 16:12'	System	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '36.8' C	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '64'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'bpm'	System	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '14'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'breaths/min'	System	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '114'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '76'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'mmHg'	System	13 Oct 2020 13:08:32

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:37

US3202070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:37

US3202070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered '16:20'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered '12 Oct 2020 16:20'	System	13 Oct 2020 13:08:50

US3202070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 13:08:58

US3202070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	13 Oct 2020 13:08:58

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 64'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-12T21:19:21', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7cc303e2-3944-4f5a-918a-c0ce88ef9d72'	System	13 Oct 2020 01:19:40
User entered 'No (N)'	System	13 Oct 2020 01:19:40

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-12T21:19:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7cc303e2-3944-4f5a-918a-c0ce88ef9d72'	System	13 Oct 2020 01:19:40
User entered 'No (N)'	System	13 Oct 2020 01:19:40

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-12T21:19:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '7cc303e2-3944-4f5a-918a-c0ce88ef9d72'	System	13 Oct 2020 01:19:40
User entered '12 Oct 2020 21:19:33'	System	13 Oct 2020 01:19:40

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 71'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-15T03:13:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b11c97fa-662c-4c4e-a9c7-f3069c7bd651'	System	15 Oct 2020 07:13:49
User entered 'No (N)'	System	15 Oct 2020 07:13:49

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-15T03:13:43', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b11c97fa-662c-4c4e-a9c7-f3069c7bd651'	System	15 Oct 2020 07:13:49
User entered 'No (N)'	System	15 Oct 2020 07:13:49

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-10-15T03:13:47', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'b11c97fa-662c-4c4e-a9c7-f3069c7bd651' User entered '15 Oct 2020 03:13:47'	System	15 Oct 2020 07:13:49
	System	15 Oct 2020 07:13:49

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 78'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:30
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 92'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-05T05:52:35', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4fed0389-1904-4702-883b-655d8f69a934'	System	05 Nov 2020 10:52:45
User entered 'No (N)'	System	05 Nov 2020 10:52:45

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-05T05:52:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4fed0389-1904-4702-883b-655d8f69a934'	System	05 Nov 2020 10:52:45
User entered 'No (N)'	System	05 Nov 2020 10:52:45

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-05T05:52:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4fed0389-1904-4702-883b-655d8f69a934'	System	05 Nov 2020 10:52:45
User entered '05 Nov 2020 05:52:42'	System	05 Nov 2020 10:52:45

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 99'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-12T00:53:53', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a75db084-b97e-42d9-89bd-aa9cf475130a'	System	12 Nov 2020 05:54:07
User entered 'No (N)'	System	12 Nov 2020 05:54:07

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-12T00:53:56', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a75db084-b97e-42d9-89bd-aa9cf475130a'	System	12 Nov 2020 05:54:07
User entered 'No (N)'	System	12 Nov 2020 05:54:07

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-12T00:54:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'a75db084-b97e-42d9-89bd-aa9cf475130a'	System	12 Nov 2020 05:54:07
User entered '12 Nov 2020 00:54:00'	System	12 Nov 2020 05:54:07

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered 'Day 106'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-19T06:17:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '22768b35-cded-44c0-84b3-09876fe423de'	System	19 Nov 2020 11:17:32
User entered 'No (N)'	System	19 Nov 2020 11:17:32

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-19T06:17:24', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '22768b35-cded-44c0-84b3-09876fe423de'	System	19 Nov 2020 11:17:32
User entered 'No (N)'	System	19 Nov 2020 11:17:32

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-11-19T06:17:29', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '22768b35-cded-44c0-84b3-09876fe423de' User entered '19 Nov 2020 06:17:29'	System	19 Nov 2020 11:17:32
	System	19 Nov 2020 11:17:32

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 15:10:20

US3202070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:24:27
Data entry locked.	System	08 Aug 2020 15:10:20
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 15:10:20

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2020-12-07T12:06:36', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e2b8eade-20e0-41d6-bb26-ac8694d68f2e'	System	07 Dec 2020 17:06:45
User entered 'No (N)'	System	07 Dec 2020 17:06:45

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2020-12-07T12:06:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e2b8eade-20e0-41d6-bb26-ac8694d68f2e'	System	07 Dec 2020 17:06:45
User entered 'No (N)'	System	07 Dec 2020 17:06:45

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-12-07T12:06:42', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'e2b8eade-20e0-41d6-bb26-ac8694d68f2e' User entered '07 Dec 2020 12:06:42'	System	07 Dec 2020 17:06:45
	System	07 Dec 2020 17:06:45

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2020-12-21T01:04:57', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '70b0163e-dd1c-4093-8fc2-a43dc809e138'	System	21 Dec 2020 06:05:09
User entered 'No (N)'	System	21 Dec 2020 06:05:09

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2020-12-21T01:05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '70b0163e-dd1c-4093-8fc2-a43dc809e138'	System	21 Dec 2020 06:05:09
User entered 'No (N)'	System	21 Dec 2020 06:05:09

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-12-21T01:05:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '70b0163e-dd1c-4093-8fc2-a43dc809e138'	System	21 Dec 2020 06:05:09
User entered '21 Dec 2020 01:05:04'	System	21 Dec 2020 06:05:09

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2020-12-28T02:04:04', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3156e50-a66d-4e6d-a8f1-deea31beb345'	System	28 Dec 2020 07:04:15
User entered 'No (N)'	System	28 Dec 2020 07:04:15

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2020-12-28T02:04:08', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3156e50-a66d-4e6d-a8f1-deea31beb345'	System	28 Dec 2020 07:04:15
User entered 'No (N)'	System	28 Dec 2020 07:04:15

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2020-12-28T02:04:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c3156e50-a66d-4e6d-a8f1-deea31beb345'	System	28 Dec 2020 07:04:15
User entered '28 Dec 2020 02:04:11'	System	28 Dec 2020 07:04:15

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-01-14T13:16:21', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '562b2780-b422-4eca-8c42-e3d47524c5b1'	System	14 Jan 2021 18:16:39
User entered 'No (N)'	System	14 Jan 2021 18:16:39

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-01-14T13:16:28', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '562b2780-b422-4eca-8c42-e3d47524c5b1'	System	14 Jan 2021 18:16:39
User entered 'No (N)'	System	14 Jan 2021 18:16:39

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-01-14T13:16:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '562b2780-b422-4eca-8c42-e3d47524c5b1'	System	14 Jan 2021 18:16:39
User entered '14 Jan 2021 13:16:33'	System	14 Jan 2021 18:16:39

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-01-18T01:03:33', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '106b03c9-66fe-4fec-b67e-bbba16f40b24'	System	18 Jan 2021 06:03:42
User entered 'No (N)'	System	18 Jan 2021 06:03:42

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-01-18T01:03:37', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '106b03c9-66fe-4fec-b67e-bbba16f40b24'	System	18 Jan 2021 06:03:42
User entered 'No (N)'	System	18 Jan 2021 06:03:42

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-01-18T01:03:40', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '106b03c9-66fe-4fec-b67e-bbba16f40b24'	System	18 Jan 2021 06:03:42
User entered '18 Jan 2021 01:03:40'	System	18 Jan 2021 06:03:42

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-01-25T00:23:55', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c34d8d16-06dd-4f23-865e-e4b46780e16a'	System	25 Jan 2021 05:24:34
User entered 'No (N)'	System	25 Jan 2021 05:24:34

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-01-25T00:24:02', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c34d8d16-06dd-4f23-865e-e4b46780e16a'	System	25 Jan 2021 05:24:34
User entered 'Yes (Y)'	System	25 Jan 2021 05:24:34

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfee1defb392)', Time: '2021-01-25T00:24:20', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c34d8d16-06dd-4f23-865e-e4b46780e16a'	System	25 Jan 2021 05:24:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 05:24:34

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-01-25T00:24:26', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c34d8d16-06dd-4f23-865e-e4b46780e16a' User entered '25 Jan 2021 00:24:26'	System	25 Jan 2021 05:24:34
	System	25 Jan 2021 05:24:34

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-02-01T00:25:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ee332d09-cc0b-44f3-9499-2eb74285b5'	System	01 Feb 2021 05:25:28
User entered 'No (N)'	System	01 Feb 2021 05:25:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-02-01T00:25:21', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ee332d09-cc0b-44f3-9499-2eb74285b5'	System	01 Feb 2021 05:25:28
User entered 'No (N)'	System	01 Feb 2021 05:25:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-02-01T00:25:24', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'ee332d09-cc0b-44f3-9499-2eb74285b5'	System	01 Feb 2021 05:25:28
User entered '01 Feb 2021 00:25:24'	System	01 Feb 2021 05:25:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-02-08T01:02:08', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8ff433cb-cfdc-4bc3-a8c8-701bd5b5d8b7'	System	08 Feb 2021 06:02:19
User entered 'No (N)'	System	08 Feb 2021 06:02:19

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-02-08T01:02:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8ff433cb-cfdc-4bc3-a8c8-701bd5b5d8b7'	System	08 Feb 2021 06:02:19
User entered 'No (N)'	System	08 Feb 2021 06:02:19

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-02-08T01:02:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '8ff433cb-cfdc-4bc3-a8c8-701bd5b5d8b7'	System	08 Feb 2021 06:02:19
User entered '08 Feb 2021 01:02:15'	System	08 Feb 2021 06:02:19

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-02-15T01:30:39', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '074de2cb-6535-40a3-82c9-015593e3560e'	System	15 Feb 2021 06:30:53
User entered 'No (N)'	System	15 Feb 2021 06:30:53

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-02-15T01:30:43', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '074de2cb-6535-40a3-82c9-015593e3560e'	System	15 Feb 2021 06:30:53
User entered 'No (N)'	System	15 Feb 2021 06:30:53

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-02-15T01:30:46', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '074de2cb-6535-40a3-82c9-015593e3560e'	System	15 Feb 2021 06:30:53
User entered '15 Feb 2021 01:30:46'	System	15 Feb 2021 06:30:53

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-02-22T05:35:11', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c8ce2629-b76c-435a-87d1-7e0279fa1a77'	System	22 Feb 2021 10:35:23
User entered 'No (N)'	System	22 Feb 2021 10:35:23

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-02-22T05:35:15', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c8ce2629-b76c-435a-87d1-7e0279fa1a77'	System	22 Feb 2021 10:35:23
User entered 'No (N)'	System	22 Feb 2021 10:35:23

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-02-22T05:35:19', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'c8ce2629-b76c-435a-87d1-7e0279fa1a77'	System	22 Feb 2021 10:35:23
User entered '22 Feb 2021 05:35:19'	System	22 Feb 2021 10:35:23

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-03-01T01:43:55-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6e511e0d-95d8-4f2b-96a5-d07bc51e50ff'	System	01 Mar 2021 06:44:04
User entered 'No (N)'	System	01 Mar 2021 06:44:04

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-03-01T01:43:58-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6e511e0d-95d8-4f2b-96a5-d07bc51e50ff'	System	01 Mar 2021 06:44:04
User entered 'No (N)'	System	01 Mar 2021 06:44:04

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-03-01T01:44:02-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6e511e0d-95d8-4f2b-96a5-d07bc51e50ff'	System	01 Mar 2021 06:44:04
User entered '01 Mar 2021 01:44:02'	System	01 Mar 2021 06:44:04

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-03-08T00:41:35-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'dbbffc6-48f8-4f70-9a06-9def077c5a32'	System	08 Mar 2021 05:41:47
User entered 'No (N)'	System	08 Mar 2021 05:41:47

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-03-08T00:41:38-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'dbbffc6-48f8-4f70-9a06-9def077c5a32'	System	08 Mar 2021 05:41:47
User entered 'No (N)'	System	08 Mar 2021 05:41:47

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-03-08T00:41:42-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: 'dbbffc6-48f8-4f70-9a06-9def077c5a32'	System	08 Mar 2021 05:41:47
User entered '08 Mar 2021 00:41:42'	System	08 Mar 2021 05:41:47

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-03-15T05:43:19-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2807f17a-51a1-4c92-9192-016536190ebb' User entered 'No (N)'	System	15 Mar 2021 09:43:28
	System	15 Mar 2021 09:43:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-03-15T05:43:22-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2807f17a-51a1-4c92-9192-016536190ebb'	System	15 Mar 2021 09:43:28
User entered 'No (N)'	System	15 Mar 2021 09:43:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-03-15T05:43:26-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2807f17a-51a1-4c92-9192-016536190ebb' User entered '15 Mar 2021 05:43:26'	System	15 Mar 2021 09:43:28
	System	15 Mar 2021 09:43:28

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-03-22T03:43:33-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4058c073-d36a-423f-8e81-7529427f5055'	System	22 Mar 2021 07:43:43
User entered 'No (N)'	System	22 Mar 2021 07:43:43

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-03-22T03:43:37-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4058c073-d36a-423f-8e81-7529427f5055'	System	22 Mar 2021 07:43:43
User entered 'No (N)'	System	22 Mar 2021 07:43:43

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-03-22T03:43:40-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '4058c073-d36a-423f-8e81-7529427f5055'	System	22 Mar 2021 07:43:43
User entered '22 Mar 2021 03:43:40'	System	22 Mar 2021 07:43:43

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-04-12T16:15:28-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2654e0b2-e7f8-480b-835a-8409199eefe3' User entered 'No (N)'	System	12 Apr 2021 20:15:40
	System	12 Apr 2021 20:15:40

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-04-12T16:15:31-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2654e0b2-e7f8-480b-835a-8409199eefe3'	System	12 Apr 2021 20:15:40
User entered 'No (N)'	System	12 Apr 2021 20:15:40

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-04-12T16:15:34-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '2654e0b2-e7f8-480b-835a-8409199eefe3'	System	12 Apr 2021 20:15:40
User entered '12 Apr 2021 16:15:34'	System	12 Apr 2021 20:15:40

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[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 (f1bcfcee1defb392)', Time: '2021-04-19T02:12:43-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6250bfc7-1bc9-47bf-9f7a-39a7584ef54c' User entered 'No (N)'	System	19 Apr 2021 06:12:52
	System	19 Apr 2021 06:12:52

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

Have you been exposed to someone with 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 (f1bcfcee1defb392)', Time: '2021-04-19T02:12:47-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6250bfc7-1bc9-47bf-9f7a-39a7584ef54c'	System	19 Apr 2021 06:12:52
User entered 'No (N)'	System	19 Apr 2021 06:12:52

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-04-19T02:12:50-04:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '6250bfc7-1bc9-47bf-9f7a-39a7584ef54c'	System	19 Apr 2021 06:12:52
User entered '19 Apr 2021 02:12:50'	System	19 Apr 2021 06:12:52

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:29:30

US3202070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:30
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:29:30

US3202070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:27:14
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	26 Mar 2021 17:49:48
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:27:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2021-03-01T01:44:09-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '288ee6b0-0536-43b7-a188-8832a7da70fc'	System	01 Mar 2021 06:44:55
User entered 'Yes (Y)'	System	01 Mar 2021 06:44:55

US3202070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:46

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfce1defb392)', Time: '2021-03-01T01:44:18-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '288ee6b0-0536-43b7-a188-8832a7da70fc' User entered 'No (N)'	System	01 Mar 2021 06:44:55
	System	01 Mar 2021 06:44:55

US3202070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:26:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1bcfcee1defb392)', Time: '2021-03-01T01:44:46-05:00', User OID: 'PatientReportedOutcome (US3202070)', ODM File OID: '288ee6b0-0536-43b7-a188-8832a7da70fc' User entered '01 Mar 2021 01:44:46'	System	01 Mar 2021 06:44:55
	System	01 Mar 2021 06:44:55

US3202070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:17:21

US3202070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:50
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:25:14
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	(b) (4), (b) (6)	03 Nov 2020 20:17:47
answered with 'IN WINDOW' (Site from System).		
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Nov 2020 20:17:21
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 20:17:21

US3202070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:17:21

US3202070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:17:21

US3202070

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:19:04

US3202070

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:34:50
User entered 'I'	System	03 Nov 2020 20:19:04

US3202070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:09:43

US3202070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:09:43

US3202070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:09:43

US3202070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:42:52
User entered 'Left message for day 119 phone call.'	(b) (4), (b) (6)	04 Dec 2020 19:09:43

US3202070

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:42:44

US3202070

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User entered 'I'	System	04 Dec 2020 19:42:44

US3202070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	10 Jan 2021 14:10:38

US3202070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) System	10 Jan 2021 14:11:14
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	10 Jan 2021 14:11:14
User entered '10 Jan 2021' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	10 Jan 2021 14:11:14
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	10 Jan 2021 14:10:38
User entered '04 Jan 2021'	zackery harmon (b) (4) (b) (4)	10 Jan 2021 14:10:38

US3202070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	10 Jan 2021 14:10:38

US3202070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) zackery harmon (b) (4)	10 Jan 2021 14:10:38
	(b) (4)	

US3202070

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	10 Jan 2021 14:11:18

US3202070

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User entered 'I'	System	10 Jan 2021 14:11:18

US3202070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:40:41

US3202070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:40:41

US3202070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:40:41

US3202070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:40:41

US3202070

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:40:48

US3202070

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:22
User entered 'I'	System	26 Feb 2021 21:40:48

US3202070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:54

US3202070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered '15 Mar 2021'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:54

US3202070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:54

US3202070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered 'VISIT4'	System	15 Mar 2021 20:58:54

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered empty.	System	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered empty.	System	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered empty.	System	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered empty.	System	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered empty.	System	31 Mar 2021 20:35:52

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06

US3202070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06

US3202070

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:59

US3202070

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:59

US3202070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:59:16

US3202070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered '15 Mar 2021'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:59:16

US3202070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:30:19
User entered '15:48'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:59:16

US3202070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered '15 Mar 2021 15:48'	System	15 Mar 2021 20:59:16

US3202070

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:59:02

US3202070

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:20:06
User entered 'I'	System	15 Mar 2021 20:59:02

US3202070

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:18
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	12 Apr 2021 20:03:07
	(b) (4)	

US3202070

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:18
	(b) (4)	
User entered '12 Apr 2021'	Lilian Nukuna (b) (4)	12 Apr 2021 20:03:07
	(b) (4)	

US3202070

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	12 Apr 2021 20:03:07
	(b) (4)	

US3202070

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	12 Apr 2021 20:03:07
	(b) (4)	

US3202070

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:18
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	12 Apr 2021 20:03:13
	(b) (4)	

US3202070

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:03:13

US3202070

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:04

US3202070

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:04

US3202070

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:04

US3202070

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:58:04

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 15:21:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:32

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark McKenzie (b) (4)	22 Apr 2021 18:36:06 22 Apr 2021 17:53:54
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 15:21:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 15:21:20
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:19:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:32

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 11:29:56
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:29:56
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '1'	System	14 Jan 2021 21:58:44

US3202070

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '1'	System	14 Jan 2021 21:58:44

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	14 Jan 2021 21:59:41
DataPoint set to visible.	System	14 Jan 2021 21:58:44

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	14 Jan 2021 21:59:41
DataPoint set to visible.	System	14 Jan 2021 21:58:44

US3202070

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '13:43'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '14 Jan 2021 13:43'	System	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '37.1' C	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '72'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'bpm'	System	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '16'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'breaths/min'	System	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '115'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '69'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 21:59:41

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	14 Jan 2021 21:59:41
DataPoint set to visible.	System	14 Jan 2021 21:58:44

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14:17'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '14 Jan 2021 14:17'	System	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 09:02:24
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Teresa Deese (b) (4)	14 Jan 2021 22:02:56
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Jan 2021 22:02:48
User entered '35.6' C	Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '63'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'bpm'	System	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '17'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'breaths/min'	System	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '134'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '82'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	14 Jan 2021 22:02:48

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:11

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:11

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mRNA-1273'	System	14 Jan 2021 22:03:32
DataPoint set to visible.	System	14 Jan 2021 21:58:44

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '13:49'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '14 Jan 2021 13:49'	System	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'ONCE'	System	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 22:03:32

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 22:04:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	14 Jan 2021 22:04:02
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 22:03:43
User entered empty.	Teresa Deese (b) (4)	14 Jan 2021 22:03:43

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:43

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '13:48'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:43

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '14 Jan 2021 13:48'	System	14 Jan 2021 22:03:43

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:55

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:55

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '13:46'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:03:55

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '14 Jan 2021 13:46'	System	14 Jan 2021 22:03:55

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 22:04:09

US3202070

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '1'	System	14 Jan 2021 22:04:09

US3202070

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Jan 2021 19:42:35

US3202070

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '21 Jan 2021'	(b) (4) Lilian Nukuna (b) (4)	21 Jan 2021 19:42:35

US3202070

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	21 Jan 2021 19:42:35

US3202070

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	21 Jan 2021 19:42:35
	(b) (4)	

US3202070

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Jan 2021 19:42:40

US3202070

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'I'	System	21 Jan 2021 19:42:40

US3202070

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '1'	System	21 Jan 2021 19:42:40
DataPoint set to visible.	System	21 Jan 2021 19:42:40

US3202070

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:26

US3202070

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '11 Feb 2021'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:26

US3202070

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:26

US3202070

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'OLD29'	System	11 Feb 2021 21:45:26

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '11 Feb 2021'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '15:52'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '11 Feb 2021 15:52'	System	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '36.7' C	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '71'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'bpm'	System	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '14'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'breaths/min'	System	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '114'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '77'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	11 Feb 2021 21:45:50

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '11 Feb 2021'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '16:40'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '11 Feb 2021 16:40'	System	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '37.1' C	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '69'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'bpm'	System	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '16'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'breaths/min'	System	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '114'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '79'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mmHg'	System	11 Feb 2021 21:46:24

US3202070

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:30

US3202070

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:30

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'mRNA-1273'	System	11 Feb 2021 21:46:43
DataPoint set to visible.	System	21 Jan 2021 19:42:40

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '11 Feb 2021'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '16:01'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '11 Feb 2021 16:01'	System	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'ONCE'	System	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 21:46:43

US3202070

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 21:46:48

US3202070

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'I'	System	11 Feb 2021 21:46:48

US3202070

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	18 Feb 2021 20:36:41

US3202070

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '18 Feb 2021'	(b) (4) Erica Osmundsen (b) (4)	18 Feb 2021 20:36:41

US3202070

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	18 Feb 2021 20:36:41

US3202070

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	18 Feb 2021 20:36:41

US3202070

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	18 Feb 2021 20:36:46

US3202070

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'I'	System	18 Feb 2021 20:36:46

US3202070

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:56:59

US3202070

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '15 Mar 2021'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:56:59

US3202070

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:56:59

US3202070

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered 'OLD57'	System	15 Mar 2021 20:56:59

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered empty.	System	15 Mar 2021 20:57:06

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12

US3202070

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12

US3202070

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
	System	15 Mar 2021 20:57:33
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	15 Mar 2021 20:57:20
User entered 'No (N)'	Teresa Deese (b) (4)	15 Mar 2021 20:57:20

US3202070

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty; reason for change Data Entry Error	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:57:33
User entered '15 Mar 2021'	Teresa Deese (b) (4)	15 Mar 2021 20:57:20

US3202070

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:00

US3202070

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '15 Mar 2021'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:00

US3202070

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '15:48'	(b) (4) Teresa Deese (b) (4)	15 Mar 2021 20:58:00

US3202070

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:19:12
User entered '15 Mar 2021 15:48'	System	15 Mar 2021 20:58:00

US3202070

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:43:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:15
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:15:23
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:57:53
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 05:41:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:00:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:03:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Mar 2021 19:50:03
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:01:59

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:03
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:05:56
User entered 'USA-US128-2021-mRNA-1273-P301000011'	System	16 Mar 2021 15:05:51
User entered 'New'	(b) (4), (b) (6)	16 Mar 2021 15:05:51

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Dysplasia cervical recurrent - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:48:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:48:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:42:04
Data point term sent to Coder	System	08 Apr 2021 12:26:43
DataPoint Un-verified.	Erica Osmundsen (b) (4)	08 Apr 2021 12:25:51
Coding entries removed.	Erica Osmundsen (b) (4)	08 Apr 2021 12:25:51
Signature has been broken.	Erica Osmundsen (b) (4)	08 Apr 2021 12:25:51
User entered 'RECURRENT CERVICAL DYSPLASIA (WITH HIGH RISK HPV)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Apr 2021 12:25:51
DataPoint Verified.		
	(b) (4), (b) (6)	05 Apr 2021 13:41:05
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Cervical dysplasia - version MedDRA\23.0.	Coder Import (b) (4)	18 Mar 2021 18:44:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Mar 2021 18:44:41
Data point term sent to Coder	System	17 Mar 2021 19:11:15
Coding entries removed.	zackery harmon (b) (4)	17 Mar 2021 19:10:35
	(b) (4)	
User entered 'Recurrent cervical dysplasia' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 19:10:35
	(b) (4)	

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Smear cervix abnormal, LLT: Abnormal cervical cytology - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 19:53:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 19:53:33
Data point term sent to Coder	System	15 Mar 2021 19:52:59
User entered 'abnormal cervical cells'	Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:08
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:10
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:11
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:58:59
User closed query 'please verify as per narrative abnormal PAP since 2019' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:34:45
Query 'please verify as per narrative abnormal PAP since 2019' answered with 'UNABLE TO ENTER ACTUAL START DATE BECAUSE IT WAS PRIOR TO START OF STUDY--THIS IS THE ISSUE CREATED BY HAVING TO ENTER PLANNED SURGERIES FOR MEDICAL HISTORY ITEMS AS AN SAE DUE TO OVERNIGHT HOSPITALIZATION WHEN THE CONDITION IS NOT EVEN AN AE' (Site from CRA).	Erica Osmundsen (b) (4)	06 Apr 2021 21:08:29
User opened query 'please verify as per narrative abnormal PAP since 2019' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 13:40:56
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '19 Feb 2021'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:15
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:16
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:41:18
User closed query 'PV Query: please confirm the event end date. as per narrative date of discharge is reported as 20 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:33:45
Query 'PV Query: please confirm the event end date. as per narrative date of discharge is reported as 20 Feb 2021.' answered with 'updated' (Site from Safety).	zackery harmon (b) (4)	22 Mar 2021 16:06:46
	(b) (4)	
Signature has been broken.	zackery harmon (b) (4)	22 Mar 2021 16:06:30
	(b) (4)	
User entered '20 Feb 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:06:30
	(b) (4)	
User opened query 'PV Query: please confirm the event end date. as per narrative date of discharge is reported as 20 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:43:40
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
	(b) (4)	
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:44:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 14:35:16
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:21
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:44
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:46
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:55
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:57
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:41:59
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:04
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '19 Feb 2021'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:06
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '20 Feb 2021'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:07
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:10
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:12
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:13
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:15
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:18
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:19
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:42:21
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:31
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:32
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '1' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 19:53:44
User entered '0'	Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:35
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:36
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:40
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:43:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:59:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:59:38
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 11:59:35
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'surgery done' (Site from Safety).	Teresa Deese (b) (4)	26 Mar 2021 17:44:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'NA' (Site from Safety).	Teresa Deese (b) (4)	26 Mar 2021 17:44:14

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'none' (Site from Safety).	Teresa Deese (b) (4)	26 Mar 2021 17:40:02
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:44:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:43:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:43:49
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'subject has had abnormal PAP x 2 since 2019 so full hysterectomy completed per GYN recommendation. SAE only because of overnight hospitalization required for this surgery.'	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 19:52:43

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:12
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms benign, HLT: Soft tissue neoplasms benign NEC, PT: Lipoma, LLT: Lipoma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 06:07:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 06:07:31
Data point term sent to Coder	System	17 Mar 2021 19:12:15
User entered 'Benign lipoma Left buttock'	zackery harmon (b) (4)	17 Mar 2021 19:11:57
	(b) (4)	

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:13
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:16
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:36
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:38
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '15 Feb 2021'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:41
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
User entered empty.	System	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:43
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:45
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '19 Feb 2021'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:47
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
User entered empty.	System	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:50
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:51
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:54
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:44:58
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:00
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:02
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:04
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:06
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:08
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:10
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:12
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:14
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:16
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:18
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:20
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:23
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:25
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:27
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'l'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:28
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:31
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:45:33
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:03:25
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
User entered '0'	System	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38
User entered 'I'	System	17 Mar 2021 19:11:57

US3202070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:38

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:18:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:18:47
Data point term sent to Coder	System	08 Apr 2021 12:17:34
User entered 'POST-SURGICAL PAIN'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User entered empty.	System	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '26 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User entered empty.	System	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'None (NONE)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'I'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:59:29
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User entered '0'	System	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42
User entered 'I'	System	08 Apr 2021 12:16:45

US3202070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:42

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:58:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:58:33
Data point term sent to Coder	System	19 Apr 2021 18:58:01
User entered 'Fatigue'	zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '08 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 18:57:19
User entered '18:00' reason for change: Data Entry Error	System	19 Apr 2021 18:57:19
User opened query 'Data is required. Please provide.' (Site from System).	zackery harmon (b) (4)	19 Apr 2021 18:57:05
User entered empty.	(b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User entered '08 Aug 2020 18:00'	System	19 Apr 2021 18:57:19
User entered empty.	System	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '18 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 18:57:19
User entered '09:00' reason for change: Data Entry Error	System	19 Apr 2021 18:57:19
User opened query 'Data is required. Please provide.' (Site from System).	zackery harmon (b) (4)	19 Apr 2021 18:57:05
User entered empty.	(b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User entered '18 Aug 2020 09:00'	System	19 Apr 2021 18:57:19
User entered empty.	System	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'I'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:54
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User entered '0'	System	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49
User entered '0'	System	19 Apr 2021 18:57:05

US3202070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:43:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:09:49

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:43:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	19 Aug 2020 20:02:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: SELECTIVE IMMUNOSUPPRESSANTS, PRODUCT: TERIFLUNOMIDE, PRODUCTSYNONYM: AUBAGIO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 20:04:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:04:34
Data point term sent to Coder	System	19 Aug 2020 20:03:50
User entered 'Aubagio'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:03:35

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Multiple Sclerosis'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '14'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:03:35
User entered '1 Jan 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:03:35
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:03:35

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:03:35

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:03:35

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: EMPAGLIFLOZIN;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: SYNJARDY XR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 20:06:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:06:33
Data point term sent to Coder	System	19 Aug 2020 20:05:58
User entered 'Synjardy XR'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:05:53

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Insulin Resistance'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '12.5/1000'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:05:53
User entered '1 Jun 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:05:53
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:05:53

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:05:53

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:05:53

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL HYDROCHLORIDE, PRODUCTSYNONYM: DONEPEZIL HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 22:38:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:38:54
Data point term sent to Coder Coding entries removed.	System Tiffany Jewell (b) (4)	14 Sep 2020 22:37:29 14 Sep 2020 22:36:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL HYDROCHLORIDE, PRODUCTSYNONYM: DONEPEZIL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 20:09:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 20:09:26
Data point term sent to Coder User entered 'Donepezil HCL'	System Tiffany Jewell (b) (4)	19 Aug 2020 20:08:03 19 Aug 2020 20:07:15

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per DM CLR: Please review if this condition should be reported as separate entry in the MH eCRF (i.e., COGNITIVE ISSUE). If yes, please add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:56:47
Query 'Per DM CLR: Please review if this condition should be reported as separate entry in the MH eCRF (i.e., COGNITIVE ISSUE). If yes, please add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'Field corrected ' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:36:49
User entered 'MULPTIPLE SCLEROSIS' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:36:39
User opened query 'Per DM CLR: Please review if this condition should be reported as separate entry in the MH eCRF (i.e., COGNITIVE ISSUE). If yes, please add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:52:18
User entered 'Cognitive Issues due to multiple sclerosis'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:07:15

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '5'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:07:15
User entered '1 Jan 2020'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:07:15
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:07:15

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:07:15

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:07:15

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 22:38:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:38:54
Data point term sent to Coder Coding entries removed.	System Tiffany Jewell (b) (4)	14 Sep 2020 22:38:30 14 Sep 2020 22:37:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 20:09:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 20:09:27
Data point term sent to Coder User entered 'Trulicity'	System Tiffany Jewell (b) (4)	19 Aug 2020 20:09:07 19 Aug 2020 20:08:16

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Insulin Resistance'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '1.5'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:57:08
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Field corrected' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:37:59
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:37:49
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:53:33
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:08:16

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:08:16
User entered '1 Jun 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:08:16
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:08:16

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:08:16

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:08:16

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:22
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:26:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:26:22
Data point term sent to Coder	System	19 Aug 2020 20:09:07
User entered 'Progesterone'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:26
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:57:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'Added to medical history' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:39:26
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:54:53
User entered 'Hot flashes'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:28
User entered '100'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:30
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:31
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:35
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:09:16
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:09:26
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:09:32
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:09:05
User entered '1 Jan 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:09:05
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:09:05
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:09:05
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:09:05
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:09:05

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 14:32:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:32:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:11:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:11:29
Data point term sent to Coder	System	19 Aug 2020 20:10:12
User entered 'Sertraline'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:10:02

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:58:17
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'Added to medical history' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 22:39:45
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:57:20
User entered 'Anxiety/Depression'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:10:02

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '100'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:10:02
User entered '1 Jan 2019'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:10:02
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:10:02

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:10:02

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:10:02

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 20:13:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:13:19
Data point term sent to Coder	System	19 Aug 2020 20:12:14
User entered 'Armour Thyroid'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:11:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Hypothyroid'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '60'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:11:14
User entered '1 Jun 2003'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:11:14
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:11:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:11:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:11:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 20:13:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:13:19
Data point term sent to Coder	System	19 Aug 2020 20:12:17
User entered 'Vitamin D3'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:12:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Multiple Sclerosis'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '1000' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 19:17:49
	(b) (4)	
User entered '5000'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'IU (IU)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:12:07
User entered '1 Jan 2007'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:12:07
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:12:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:12:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:12:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 06:46:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:46:18
Data point term sent to Coder	System	19 Aug 2020 20:13:19
User entered 'Fish Oil'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:13:06

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Multiple Sclerosis'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '1400'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:03:54
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	19 Aug 2020 20:13:06
User entered '1 Jan 2007'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	19 Aug 2020 20:13:06
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:13:06

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 20:13:06

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 20:13:06

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
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)	27 Oct 2020 14:06:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:06:23
Data point term sent to Coder	System	27 Oct 2020 13:52:23
User entered 'flu shot'	Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'flu prevention'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '0.5'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'mL (mL)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'once (ONCE)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '29 Sep 2020'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '0'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '29 Sep 2020'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User entered empty.	System	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User entered empty.	System	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:47
User entered empty.	System	27 Oct 2020 13:51:43

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTSYNONYM: ESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:07:19
Data point term sent to Coder	System	27 Oct 2020 13:59:31
Data point term sent to Coder	System	27 Oct 2020 13:58:31
User entered 'estrogen patch'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'hot flashes' reason for change: Data Entry Error	Teresa Deese (b) (4)	27 Oct 2020 13:59:30
User entered 'postmenopausal'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0.025'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'every week (QS)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Transdermal (TRANSDERMAL)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'UN Sep 2020'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	27 Oct 2020 13:57:59

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:19:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:19:24
Data point term sent to Coder	System	04 Nov 2020 14:19:12
User entered 'phentermine' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 14:18:12
Data point term sent to Coder	System	04 Nov 2020 14:18:09
Coding entries removed.	Teresa Deese (b) (4)	04 Nov 2020 14:17:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:24:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:24:22
Data point term sent to Coder	System	03 Nov 2020 20:29:06
User entered 'Phentremine'	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'obesity' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 14:17:57
User entered 'Weight loss'	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 09:51:55
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct dosage should have been 37.5 mg' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:25:04
User entered '37.5' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Dec 2020 15:24:31
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 16:11:32
User entered '25' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 20:47:48
User entered 'n/a'	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:47:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 20:47:48
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 20:47:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:28:14
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 20:28:59
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:28:14
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'UN UNK 2019' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 14:17:57
User entered '28 Oct 2019'	(b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:28:59
User entered empty.	System	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:28:59
User entered empty.	System	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:28:59
User entered empty.	System	03 Nov 2020 20:28:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 12:35:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 12:35:43
Data point term sent to Coder	System	08 Apr 2021 12:26:43
Coding entries removed.	Erica Osmundsen (b) (4)	08 Apr 2021 12:26:39
User closed query 'Medication records/additional hospital records will have additional information needed for SAE treatment. Please verify these have been requested.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:51:01
Query 'Medication records/additional hospital records will have additional information needed for SAE treatment. Please verify these have been requested.' answered with 'requested and received some additional medication details' (Site from CRA).	Erica Osmundsen (b) (4)	07 Apr 2021 15:49:01
User opened query 'Medication records/additional hospital records will have additional information needed for SAE treatment. Please verify these have been requested.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:40:40
User closed query 'Please verify that medication administration records have been requested from facility' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:40:40
Query 'Please verify that medication administration records have been requested from facility' answered with 'what has that got to do with gen anes?' (Site from CRA).	Teresa Deese (b) (4)	07 Apr 2021 14:19:48
User opened query 'Please verify that medication administration records have been requested from facility' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 13:50:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:49:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:58:07
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.	Teresa Deese (b) (4)	29 Mar 2021 17:01:00
' answered with 'name of anesthesia unknown & not in chart' (Site from DM).		
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.	(b) (4), (b) (6)	29 Mar 2021 02:34:56
' (Site from DM).		
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:40:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:40:49
Data point term sent to Coder	System	15 Mar 2021 19:58:02
User entered 'general anesthesia'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:49:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:06
DataPoint Un-verified.	Erica Osmundsen (b) (4)	08 Apr 2021 12:26:39
User entered 'RECURRENT CERVICAL DYSPLASIA (WITH HIGH RISK HPV) SURGICAL MEDICATION' reason for change:	Erica Osmundsen (b) (4)	08 Apr 2021 12:26:39
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:49:54
User entered 'abnormal cervical cells (hysterectomy)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:49:56
User entered 'unk'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:49:58
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:00
User entered 'unknown'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:02
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:04
User entered empty.	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:06
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:08
User entered empty.	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:09
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:11
User entered '0'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:13
User entered 'No (N)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:16
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:18
User entered 'No (N)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User entered empty.	System	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User entered empty.	System	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:54
User entered empty.	System	15 Mar 2021 19:57:14

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component (e.g Calcium/ Vitamin D3. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 10:58:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;VITAMIN D NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:57:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:57:47
Query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component (e.g Calcium/ Vitamin D3. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	29 Mar 2021 17:02:28
Data point term sent to Coder	System	29 Mar 2021 17:02:21
Coding entries removed.	Teresa Deese (b) (4)	29 Mar 2021 17:02:09
User entered 'CALCIUM CITRATE/vit d' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 17:02:09
User opened query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component (e.g Calcium/ Vitamin D3. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:35:09

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[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 CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 19:43:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 19:43:48
Data point term sent to Coder	System	17 Mar 2021 19:42:26
User entered 'calcium citrate'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Supplement'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '315/250'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Other (OTHER)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg/units'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'twice daily (BID)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'un UNK 2015'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:42:22
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 19:42:22

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 19:42:22

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 19:42:22

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 21:24:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:24:50
Data point term sent to Coder	System	17 Mar 2021 19:43:27
User entered 'Coenzyme Q10'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:43:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Multiple sclerosis'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '100'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'twice daily (BID)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'un UNK 2010'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:43:03
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 19:43:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 19:43:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 19:43:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 19:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 19:47:55
Data point term sent to Coder	System	17 Mar 2021 19:46:30
User entered 'Fexofenadine'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:45:51

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Seasonal allergies'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '180'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'as needed (PRN)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'un UNK 2020'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:45:51
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 19:45:51

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 19:45:51

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 19:45:51

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 22:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 22:00:49
Data point term sent to Coder	System	17 Mar 2021 19:47:31
User entered 'Lactobacillus'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:46:41

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Pobiotic gut health'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '1'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'capsule (CAPSULE)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'once daily (QD)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'un UNK 2015'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:46:41
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 19:46:41

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 19:46:41

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 19:46:41

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ZEAXANTHIN, PRODUCTSYNONYM: LUTEIN [ZEAXANTHIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 09:28:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:28:30
Data point term sent to Coder	System	17 Mar 2021 19:47:31
User entered 'Lutein'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:47:09

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Eye prophlaxis'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '40'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'three times daily (TID)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'un UNK 2017'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	17 Mar 2021 19:47:09
	(b) (4)	

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 19:47:09

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 19:47:09

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 19:47:09

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 17:54:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:54:28
Data point term sent to Coder	System	26 Mar 2021 17:53:29
User entered 'botox'	Teresa Deese (b) (4) (b) (4) (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'cosmetic'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'unk'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:23:50
Query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' answered with 'correct' (Site from DM).	Teresa Deese (b) (4)	06 Apr 2021 14:32:57
User opened query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:07:12
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'units'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'UN UNK 2010'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:52:57

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 17:56:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:56:29
Data point term sent to Coder	System	26 Mar 2021 17:55:33
User entered 'juvederm'	Teresa Deese (b) (4) (b) (4) (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'cosmetic'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'unk'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User closed query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:23:59
Query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' answered with 'correct' (Site from DM).	Teresa Deese (b) (4)	06 Apr 2021 14:33:12
User opened query 'Per CDM: Please verify that Dose per administration is UNK however Dose unit and related fields are provided with data. Please review and update accordingly. Else clarify ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:07:25
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'units'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'UN UNK 2010'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:55:12

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:25:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:25:55
Data point term sent to Coder	System	07 Apr 2021 16:25:16
User entered 'ACETAMINOPHEN'	Erica Osmundsen (b) (4) 	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:37
User entered 'pre-surgical pain prevention'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:41
User entered '1000'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:44
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:45
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:48
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:50
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:52
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:55
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:57
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:45:59
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:01
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:03
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:05
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User entered empty.	System	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User entered empty.	System	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:04
User entered empty.	System	07 Apr 2021 16:24:36

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:50:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:50:39
Data point term sent to Coder	System	07 Apr 2021 16:37:50
User entered 'marcaine 0.5%'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:12
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:14
User entered 'benign lipoma left buttock'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:18
User entered '5'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:21
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:22
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:24
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:25
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:30
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:32
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:34
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:36
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:38
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:40
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User entered empty.	System	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User entered empty.	System	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:10
User entered empty.	System	07 Apr 2021 16:37:07

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:22:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:22:44
Data point term sent to Coder	System	08 Apr 2021 12:18:35
User closed query 'CDM-Coding: The trade name ANCEF can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	08 Apr 2021 12:17:35
Query 'CDM-Coding: The trade name ANCEF can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' answered with 'UPDATED' (Site from System).	Erica Osmundsen (b) (4)	08 Apr 2021 12:17:35
Data point term sent to Coder	System	08 Apr 2021 12:17:34
User entered 'ANCEF (CEFAZOLIN)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Apr 2021 12:17:30
User opened query 'CDM-Coding: The trade name ANCEF can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:49:34

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
' (Site from System).	System	07 Apr 2021 16:45:59
Data point term sent to Coder	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32
User entered 'ANCEF'		

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:51
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:46:49
User entered 'SURGICAL PROCEDURE FOR INFECTION PROPHYLAXIS'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:08
User entered '2'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:10
User entered 'g (g)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:12
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:14
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:15
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:18
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:20
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:21
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:24
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:28
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:31
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered empty.	System	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered empty.	System	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered empty.	System	07 Apr 2021 16:45:32

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:43
Data point term sent to Coder	System	07 Apr 2021 16:50:14
User entered 'COLACE'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:41
User entered 'PREVENTION OF OPIOID-INDUCED CONSTIPATION POST SURGICAL PROCEDURE'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:44
User entered '100'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:45
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:47
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:48
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:50
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:52
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:54
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:56
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:49:58
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:04
User entered '20 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:06
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User entered '1'	System	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User entered '1'	System	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:29
User entered '804 (804)'	System	07 Apr 2021 16:49:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: DRONABINOL, PRODUCTSYNONYM: MARINOL [DRONABINOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:52:46
Data point term sent to Coder	System	07 Apr 2021 16:53:20
User entered 'MARINOL'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:14
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:16
User entered 'NAUSEA PREVENTION PRIOR TO SUGERY'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:19
User entered '2.5'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:21
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:23
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:25
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:27
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:29
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:31
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:33
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:36
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:38
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:40
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:42
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User entered empty.	System	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User entered empty.	System	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:35
User entered empty.	System	07 Apr 2021 16:52:58

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:54:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:54:40
Data point term sent to Coder	System	07 Apr 2021 17:04:50
User entered 'NEURONTIN'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:54
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:55
User entered 'PAIN PROPHYLAXIS PRE-SURGERY'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:58
User entered '400'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:59
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:01
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:02
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:04
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:06
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:08
User entered empty.	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:10
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:13
User entered '0'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:16
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:17
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User entered empty.	System	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User entered empty.	System	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:46
User entered empty.	System	07 Apr 2021 17:04:28

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:46:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:46:21
Data point term sent to Coder	System	08 Apr 2021 12:19:36
User entered 'NORCO (HYDROCODONE 5MG / ACETAMINOPHEN 325MG PER TABLET)'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:33
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:35
User entered 'POST-SURGICAL PAIN'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:37
User entered 'I'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:39
User entered 'tablet (TABLET)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:41
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:48
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:50
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:52
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:55
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:56
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:59
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:52:00
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:52:02
User entered '20 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:52:05
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User entered empty.	System	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User entered empty.	System	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:54
User entered empty.	System	08 Apr 2021 12:19:10

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:29:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:29:50
Data point term sent to Coder	System	08 Apr 2021 12:20:37
User entered 'TORADOL'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:34
User entered 'POST-SURGICAL PAIN'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:37
User entered '30'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:39
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:41
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:43
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:45
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:47
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:48
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:52
User entered '20 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:54
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:56
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:54:58
User entered '20 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:00
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User entered empty.	System	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User entered empty.	System	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:04
User entered empty.	System	08 Apr 2021 12:20:01

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:23:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:23:47
Data point term sent to Coder	System	08 Apr 2021 12:21:39
User entered 'LACTATED RINGERS'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:08
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:10
User entered 'PROCEDURAL MEDICATION (TO MAINTAIN IV LINE)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:13
User entered '125'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:16
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:18
User entered 'ML/HR'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:19
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:21
User entered 'CONTINUOUS'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:24
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:25
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:27
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:30
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:34
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:36
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User entered empty.	System	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User entered empty.	System	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:10
User entered empty.	System	08 Apr 2021 12:21:20

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:24:51
Data point term sent to Coder	System	08 Apr 2021 12:23:40
User entered 'LACTATED RINGERS'	Erica Osmundsen (b) (4) 	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:47
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:55:49
User entered 'PROCEDURAL MEDICATION TO MAINTAIN IV'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:21:36
User closed query 'source = 100 mL/hr, please verify' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:21:34
Query 'source = 100 mL/hr, please verify' answered with 'DONE' (Site from CRA).	Erica Osmundsen (b) (4)	08 Apr 2021 16:15:53
User entered '100' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Apr 2021 16:00:52
User opened query 'source = 100 mL/hr, please verify' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:56:34
User entered '125'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:37
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:39
User entered 'ML/HR'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:42
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:44
User entered 'CONTINUOUS'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:46
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:47
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:50
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:51
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:55
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:56:57
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User entered empty.	System	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User entered empty.	System	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:16
User entered empty.	System	08 Apr 2021 12:23:03

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:39:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:39:46
Data point term sent to Coder	System	08 Apr 2021 12:23:40
User entered 'REGLAN'	Erica Osmundsen (b) (4) 	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:05
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:07
User entered 'PRE-SURGICAL NAUSEA PREVENTION'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:09
User entered '10'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:13
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:15
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:16
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:18
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:20
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:22
User entered empty.	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:24
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:26
User entered '0'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:31
User entered '19 Feb 2021'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:57:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered empty.	System	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered empty.	System	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:43:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered empty.	System	08 Apr 2021 12:23:40

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:43:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:06:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	15 Mar 2021 19:52:53
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	19 Aug 2020 20:16:43

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered '19 Feb 2021'	Erica Osmundsen (b) (4) 	15 Mar 2021 19:53:24

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered 'total hysterectomy'	Erica Osmundsen (b) (4) 	15 Mar 2021 19:53:24

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User closed query 'Per CDM: Please verify the indication as it is noted as 'Adverse Event', which is not expected to be, as there is no corresponding Condition related to this Procedure . Kindly review Medical History and update the Indication accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:58:51
Query 'Per CDM: Please verify the indication as it is noted as 'Adverse Event', which is not expected to be, as there is no corresponding Condition related to this Procedure . Kindly review Medical History and update the Indication accordingly, Else clarify.'	Teresa Deese (b) (4)	19 Mar 2021 17:12:36
answered with 'look at AEs again' (Site from DM).		
User opened query 'Per CDM: Please verify the indication as it is noted as 'Adverse Event', which is not expected to be, as there is no corresponding Condition related to this Procedure . Kindly review Medical History and update the Indication accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:57:43
Query 'Per CDM: Please verify the indication as it is noted as 'Adverse Event', which is not expected to be. Kindly review MH # 5 as it may be related to this Concomitant Procedure and update the Indication accordingly, Else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:54:35
User opened query 'Per CDM: Please verify the indication as it is noted as 'Adverse Event', which is not expected to be. Kindly review MH # 5 as it may be related to this Concomitant Procedure and update the Indication accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:54:06
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	15 Mar 2021 19:53:24

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:46

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered empty.	Erica Osmundsen (b) (4)	15 Mar 2021 19:53:24

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered '19 Feb 2021'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:41

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered 'Bilateral salpingo-cophorectomy'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:41

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered 'Adverse Event (AE)'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:41

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered empty.	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:41

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered '19 Feb 2021'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:58

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered 'Excision of l buttock lipoma'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:58

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered 'Adverse Event (AE)'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:58

US3202070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:05
User entered empty.	zackery harmon (b) (4) (b) (4)	17 Mar 2021 19:12:58

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
User entered '16/Mar/2021 11:06'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
User entered '18/Mar/2021 08:50'	System	18 Mar 2021 12:50:37

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 12:50:37

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
User entered '23/Mar/2021 14:34'	System	23 Mar 2021 19:34:14

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 19:34:14

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:43:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
User entered '29/Mar/2021 08:03'	System	29 Mar 2021 12:03:49

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:43:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:11:38
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:46:41
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 12:03:49

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'USA-US128-2021-MRNA-1273-P301000011'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Yes (Y)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'No (N)'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'Mark'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:06:22
User entered 'McKenzie'	System	16 Mar 2021 15:05:51

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '6035 SHALLOWFORD ROAD STE 109' reason for change: Data Entry Error	zackery harmon (b) (4)	17 Mar 2021 20:38:30
User entered '6035 shallowford road'	(b) (4) zackery harmon (b) (4)	17 Mar 2021 20:38:15
	(b) (4)	

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'Chattanooga' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:30
User entered 'ste 109'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'TN'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 19:34:21
Un-reviewed for Safety.	System	18 Mar 2021 12:50:37
User entered empty.	System	18 Mar 2021 12:50:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered '37421'	zackery harmon (b) (4) (b) (4)	17 Mar 2021 20:38:15

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:46:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:50:23
User entered 'US'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 19:11:53
User entered '4'	System	29 Mar 2021 12:03:49
User entered '3'	System	23 Mar 2021 19:34:14
User entered '2'	System	18 Mar 2021 12:50:37
User entered '1'	System	16 Mar 2021 15:06:31

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:43:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:06:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered '08/Apr/2021 14:11'	(b) (4) System	08 Apr 2021 19:11:53

US3202070

Folder: SAE USA-US128-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:43:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:06:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:29:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:11:53