

US3532063 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:08:04

All time stamps listed in this document are displayed in GMT

US3532063

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

[Participant ID](#)

US3532063

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

US3532063

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	OSTEOARTHRITIS
	NECK AND LEGS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	GANGLION CYST
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1978
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	CYST ON NECK BENIGN
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	BREAST NODE - BENIGN
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532063

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:49 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:49
Height (<i>xxx.x</i>)	169.5 cm
Weight (<i>xxx.x</i>)	49.9 kg
BMI (<i>xxx.x</i>)	17.36845 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*) 18 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 10:54:21

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186760

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

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)	18 AUG 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:45
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:20
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 14:41 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 14:41

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	14:21 (24 HR)
Collection date and time (derived)	18 AUG 2020 14:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:11	18 AUG 2020 14:11
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

97.5 °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 18 AUG 2020 15:21

PC Open Date & Time 18 AUG 2020 15:01

PC Close Date & Time 18 AUG 2020 17:31

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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 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):

PC Time Stamp	18 AUG 2020 21:15
PC Open Date & Time	18 AUG 2020 18:26
PC Close Date & Time	19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

19 AUG 2020 21:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 20:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

97.5 °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 AUG 2020 22:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

96.2 °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

22 AUG 2020 21:27

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

96.7 °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

23 AUG 2020 21:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

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):

PC Time Stamp

25 AUG 2020 01:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

18 AUG 2020 15:22

PC Open Date & Time

18 AUG 2020 15:01

PC Close Date & Time

18 AUG 2020 17:31

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

18 AUG 2020 21:16

PC Open Date & Time

18 AUG 2020 18:26

PC Close Date & Time

19 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

19 AUG 2020 21:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

8

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 20:08

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

21 AUG 2020 22:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

22 AUG 2020 21:28

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

23 AUG 2020 21:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 01:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 15:23
PC Open Date & Time	18 AUG 2020 15:01
PC Close Date & Time	18 AUG 2020 17:31

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 21:17
PC Open Date & Time	18 AUG 2020 18:26
PC Close Date & Time	19 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

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 ☒

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EAB) (1725)

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US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:20
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:09
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:29
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:29
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 01:15
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:09
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	15:43 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 15:43
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 15:11 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 15:11

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

US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	16 SEP 2020 14:50

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:37	16 SEP 2020 14:37
Nasopharyngeal Swab 2	No		

US3532063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

16 SEP 2020 15:43

PC Open Date & Time

16 SEP 2020 15:31

PC Close Date & Time

16 SEP 2020 18:01

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	16 SEP 2020 21:21
PC Open Date & Time	16 SEP 2020 18:56
PC Close Date & Time	17 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 04:43

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

95.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:59

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 21:06

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

97.1 °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

21 SEP 2020 21:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

97.1 °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

22 SEP 2020 21:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 15:44

PC Open Date & Time

16 SEP 2020 15:31

PC Close Date & Time

16 SEP 2020 18:01

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:22

PC Open Date & Time

16 SEP 2020 18:56

PC Close Date & Time

17 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 04:44

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

300

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 21:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

21 SEP 2020 21:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 21:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 15:45
PC Open Date & Time	16 SEP 2020 15:31
PC Close Date & Time	16 SEP 2020 18:01

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:23
PC Open Date & Time	16 SEP 2020 18:56
PC Close Date & Time	17 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:52
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

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)

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 04:44
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

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 ☒

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:03
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 10:54:20

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:06:40

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:36
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

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.

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

13:54 (24 HR)

Collection date and time (derived)

14 OCT 2020 13:54

US3532063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:06:41

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

18 OCT 2020 12:04:16

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

25 OCT 2020 07:39:59

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 NOV 2020 18:10:23
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

15 NOV 2020 07:23:35

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 14:24:12
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 00:22:33

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 06:11:22

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 06:00:47

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

17 DEC 2020 13:36:18

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 13:10:40

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 06:28:44

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

07 JAN 2021 05:49:00

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 21:22:02

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

21 JAN 2021 12:23:29

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

28 JAN 2021 06:04:01

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 06:26:32

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

11 FEB 2021 09:18:02

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

19 FEB 2021 12:21:09

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

25 FEB 2021 11:59:36

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 MAR 2021 06:17:29
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

11 MAR 2021 08:25:01

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

18 MAR 2021 04:59:36

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

25 MAR 2021 06:15:52

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

01 APR 2021 12:51:17

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 06:52:05

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 12:22:03

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

22 APR 2021 07:05:45

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

29 APR 2021 11:26:51

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	29 NOV 2021 23:59
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US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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°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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 <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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3532063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:08:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 21:34:07

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:35:08

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:35:08

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 08:24:18

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT4

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:27 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:27
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

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.

US3532063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	11 MAR 2021 08:35

US3532063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 15:47:00

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 15:47:00

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532063

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:04

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"/>

US3532063

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:08:04

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532063

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

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

Visit date (dd MMM yyyy)	13 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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US3532063

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 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>)	13 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

US3532063

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

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

US3532063

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 08:46
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 10:01
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3532063

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 09:30 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 09:30

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

US3532063

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

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

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00-23:59)	09:05 (24 HR)
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Collection date and time (derived)	13 JAN 2021 09:05
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US3532063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	08:55
Collection Date and Time (derived)	13 JAN 2021 08:55

US3532063

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

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)	08:03 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:03
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

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)	11 FEB 2021
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:29
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 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)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3532063

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3532063

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

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) 08:57 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 08:57

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

What was the frequency of the study treatment dosing? ONCE

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

US3532063

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532063

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:58:27

Generated On: 10 Jun 2021 08:08:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532063

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:27 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:27
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532063

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

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.

US3532063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:58:24

Generated On: 10 Jun 2021 08:08:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	11 MAR 2021 08:35

US3532063

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:07:57

Generated On: 10 Jun 2021 08:08:04

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 08:36:46

Generated On: 10 Jun 2021 08:08:04

AEID	USA-US077-2020-MRNA-1273-P30 1000007
Adverse event	FRACTURED LEFT FEMUR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	01 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

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

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Folder: Adverse Events

Form: Adverse Events (1)

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WHILE OUT OF TOWN,
SUBJECT FELL AND
FRACTURED L FEMUR.
HOSPITALIZED AND
SURGICALLY REPAIRED. HAS
BEEN DISCHARGED FOR
REHAB AND IS STILL OUT OF
STATE. WILL OBTAIN
HOSPITAL RECORDS

RECORDS PROVIDED 11-17-20
SUBJECT WAS FOLLOWED BY
INTERIM ORTHOPEDIC GROUP
PRIOR TO RETURNING HOME.
END DATE WAS DETERMINED
BY HOME ORTHOPEDIC
ASSESSMENT DONE UPON
RETURN FROM OUT OF STATE.

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

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Folder: Adverse Events

Form: Adverse Events (2)

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AEID

Adverse event

POST SURGICAL PAIN (REPAIR
OF FRACTURED FEMUR)

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 18:58:00

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication OMEGA 3

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 1200

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)

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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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (3)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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Name of Medication TUMERIC

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication 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 (4)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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Name of Medication SUPER B VITAMIN

Prophylaxis Yes ☒
No ☐

Indication 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 (5)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 18:58:00

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 5000

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) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 500/400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication FLU AD

Prophylaxis Yes ☒
No ☐

Indication ANNUAL FLU VACCINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL DVT
PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication FLEXERIL

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL MUSCLE LEG
SPASMS FOLLOWING REPAIR
OF FRACTURED FEMUR

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 (11)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication COLACE

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL
CONSTIPATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication PERCOSET

Prophylaxis Yes ☐
No ☒

Indication POSTSURGICAL LEG PAIN -
FOLLOWING REPAIR OF
FRACTURED FEMUR

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication PROPOFOL INJECTION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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 (16)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication LIDOCAINE (PF) 1% INJECTION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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 (17)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication ROCURONIUM INJECTION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication FENTANYL INJECTION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 8

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication BRIDION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication ANCEF

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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 (25)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication 0.9% SODIUM CHLORIDE
INFUSION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

Dose per administration 10-125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

	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 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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

Name of Medication LACTATED RINGERS INFUSION

Prophylaxis Yes ☐
No ☒

Indication CONCOMITANT PROCEDURE #
1. SURGICAL REPAIR OF L
FEMORAL FRACTURE

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 18:58:00

Generated On: 10 Jun 2021 08:08:04

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

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 18:58:23

Generated On: 10 Jun 2021 08:08:04

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 08:36:46

Generated On: 10 Jun 2021 08:08:04

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	SURGICAL REPAIR OF LEFT FRACTURED FEMUR	Adverse Event	
1 DEC 2020	PHYSICAL THERAPY	Adverse Event	
28 OCT 2020	XRAY OF HIPS AND PELVIS	Adverse Event	
29 OCT 2020	XRAY OF HIP AND PELVIS	Adverse Event	

US3532063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:04

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3532063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:08:04

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 ☐

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/NOV/2020 12:44
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

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/NOV/2020 09:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/NOV/2020 08:46
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.	True

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/JAN/2021 12:10
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

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/FEB/2021 11:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/FEB/2021 11:11
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

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:04
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

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Data signed: (b) (4) 16 Apr 2021 08:36:47

Generated On: 10 Jun 2021 08:08:04

SAEID	USA-US077-2020-MRNA-1273-P301000007
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 14:56
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

US3532063 (Prod: Children's Healthcare of Atlanta)

US3532063

Form: Participant Creation

Generated On: 10 Jun 2021 08:08:04

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'US3532063'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:29:48

US3532063

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 17:51:34

US3532063

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:29:49

US3532063

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	18 Aug 2020 17:51:34

US3532063

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'SCRN'	System	18 Aug 2020 17:51:34

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:29:50

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '70'	(b) (4) Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'YEARS'	System	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '70'	System	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Female (F)'	(b) (4) Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'I'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:00

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Aug 2020'	System	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2020'	System	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Amendment 2 (2)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:19

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:29:49

US3532063

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'I'	System	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:08:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:35:10

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 05:43:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 05:43:33
Data point term sent to Coder	System	22 Aug 2020 18:24:52
User entered 'OSTEOARTHRITIS'	Kathy Stephens (b) (4)	22 Aug 2020 18:23:53
Neck and Legs' reason for change: Data Entry Error		
Data point term sent to Coder	System	22 Aug 2020 18:22:49
User entered 'Osteoarthritis'	Kathy Stephens (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2000'	Kathy Stephens (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2000'	System	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2000'	System	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:22:34

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Ganglion cyst - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
Data point term sent to Coder	System	22 Aug 2020 18:23:51
User entered 'ganglion cyst'	Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'I'	Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	(b) (4) Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 1978'	Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 1978'	System	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '1978'	System	22 Aug 2020 18:23:16

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Mass conditions NEC, PT: Cyst, LLT: Cyst - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:57:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:57:26
Data point term sent to Coder	System	22 Aug 2020 18:25:53
User entered 'CYST ON NECK benign' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:25:51
Data point term sent to Coder	System	22 Aug 2020 18:24:53
User entered 'Cyst on nect'	Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2017'	Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	(b) (4) Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2017'	Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2017'	System	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2017'	System	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2017'	System	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2017'	System	22 Aug 2020 18:24:43

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Benign breast neoplasm - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:44
Data point term sent to Coder	System	22 Aug 2020 18:25:53
User entered 'Breast node - Benign'	Kathy Stephens (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2010'	Kathy Stephens (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2010'	Kathy Stephens (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2010'	System	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2010'	System	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2010'	System	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2010'	System	22 Aug 2020 18:25:23

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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)	22 Aug 2020 18:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:28:12
Data point term sent to Coder	System	22 Aug 2020 18:26:54
User entered 'Seasonal Allergies'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'I'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:19

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	22 Aug 2020 18:27:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:27:13
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	22 Aug 2020 18:26:19
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:19

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:28:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:28:13
Data point term sent to Coder	System	22 Aug 2020 18:27:54
User entered 'Latex allergy'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2000'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2000'	System	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2000'	System	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	22 Aug 2020 18:26:57

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:07:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:07:39
Data point term sent to Coder	System	04 Sep 2020 18:07:19
User entered 'Menopause'	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'UN UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Kathy Stephens (b) (4)	04 Sep 2020 18:07:18
User entered 'un UNK 2004'	(b) (4)	
	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'Jan 2000'	System	04 Sep 2020 18:07:18
User entered 'Jan 2004'	System	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '2000'	System	04 Sep 2020 18:07:18
User entered '2004'	System	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered empty.	System	04 Sep 2020 18:06:47

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	22 Aug 2020 18:30:28
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	22 Aug 2020 18:30:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:30:28
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	22 Aug 2020 18:30:20
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	18 Aug 2020 18:36:28
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Aug 2020 18:30:39
User entered '18 Aug 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:30:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Aug 2020 18:30:28
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '13:49' reason for change: Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered '18 Aug 2020 13:49'	System	22 Aug 2020 18:30:39
User entered empty.	System	18 Aug 2020 18:36:28

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '169.5' cm	(b) (4) Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
DataPoint set to visible.	(b) (4) System	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '49.9' kg	(b) (4) Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
DataPoint set to visible.	(b) (4) System	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
Amendment Manager: User entered '17.36845'	System	17 Sep 2020 00:12:24
User entered '17.4'	System	18 Aug 2020 18:36:28
DataPoint set to visible.	System	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'kg/m2'	System	18 Aug 2020 18:36:28
DataPoint set to visible.	System	18 Aug 2020 18:35:01

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 18:36:28

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'bpm'	System	22 Aug 2020 18:30:20
User entered empty.	System	18 Aug 2020 18:36:28

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'breaths/min'	System	22 Aug 2020 18:30:20
User entered empty.	System	18 Aug 2020 18:36:28

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'mmHg'	System	22 Aug 2020 18:30:20
User entered empty.	System	18 Aug 2020 18:36:28

US3532063

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:30:20
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:36:28
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User entered 'mmHg'	System	22 Aug 2020 18:30:20
User entered empty.	System	18 Aug 2020 18:36:28

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Sep 2020 13:24:18
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:53:26

US3532063

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	18 Sep 2020 13:24:18
User entered empty; reason for change Data Entry Error	Kathy Stephens (b) (4)	18 Sep 2020 13:24:18
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	16 Sep 2020 18:40:16
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:53:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

US3532063

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

US3532063

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 08:37:25
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'added ti MH' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	04 Sep 2020 18:08:27
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:51:44
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 18:54:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

US3532063

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'un UNK 2000'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:04

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
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	18 Aug 2020 18:55:32
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Aug 2020 18:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 18:54:58
	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58
	(b) (4)	

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'I'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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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)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '0'	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:54:58

US3532063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:41

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:41

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	18 Aug 2020 17:52:41

US3532063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'VISIT1'	System	18 Aug 2020 17:52:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 18:14:41

US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:21:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:21:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 18:14:41
User entered '186760' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 18:14:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 18:14:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:55:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:55:52

US3532063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:55:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:55:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 18:55:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 15:08:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User accepted default value 'Pre-Dose (PREDOSE)'	Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '13:45'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered '18 Aug 2020 13:45'	System	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '97.1' F	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '76'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'bpm'	System	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Aug 2020 21:03:24
User entered '18' reason for change: Data Entry Error	System	22 Aug 2020 21:03:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kathy Stephens (b) (4)	22 Aug 2020 21:03:24
User entered "18" (non-conformant).	(b) (4)	18 Aug 2020 18:57:33
	System	18 Aug 2020 18:57:33
	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'breaths/min'	System	22 Aug 2020 21:03:24
User entered empty.	System	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '103'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'mmHg'	System	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '64'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'mmHg'	System	18 Aug 2020 18:57:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Aug 2020 18:32:27
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:57:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User accepted default value 'Post-Dose (POSTDOSE)'	Kathy Stephens (b) (4) (b) (4)	22 Aug 2020 18:32:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
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	22 Aug 2020 18:34:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	22 Aug 2020 18:32:27
	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '15:20' reason for change: Data Entry Error	(b) (4)	22 Aug 2020 18:34:43
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered '18 Aug 2020 15:20'	System	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Aug 2020 18:35:03
User entered '97.4' F reason for change: Data Entry Error	System	22 Aug 2020 18:35:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kathy Stephens (b) (4)	22 Aug 2020 18:35:03
User entered '97.4' (non-conformant).	(b) (4)	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:34:43
	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
	(b) (4)	22 Aug 2020 18:32:27
	Kathy Stephens (b) (4)	
	(b) (4)	

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '65' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	(b) (4)	
	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27
	(b) (4)	

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'bpm'	System	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	(b) (4)	
	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27
	(b) (4)	

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'breaths/min'	System	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '115' reason for change: Data Entry Error	(b) (4) Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	(b) (4) Kathy Stephens (b) (4)	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'mmHg'	System	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '76' reason for change: Data Entry Error	Kathy Stephens (b) (4)	22 Aug 2020 18:34:43
User entered empty.	Kathy Stephens (b) (4)	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'mmHg'	System	22 Aug 2020 18:34:43
User entered empty.	System	22 Aug 2020 18:32:27

US3532063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:45

US3532063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:57:45

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:41'	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered '18 Aug 2020 14:41'	System	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Left Arm (LEFT ARM)'	Kathy Stephens (b) (4)	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'ONCE'	System	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 18:58:25

US3532063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 18:59:16

US3532063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 18:59:16

US3532063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:21'	Kathy Stephens (b) (4)	18 Aug 2020 18:59:16

US3532063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered '18 Aug 2020 14:21'	System	18 Aug 2020 18:59:16

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '18 Aug 2020'	Kathy Stephens (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:11'	Kathy Stephens (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered '18 Aug 2020 14:11'	System	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kathy Stephens (b) (4) (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered empty.	System	18 Aug 2020 19:00:09

US3532063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	22 Aug 2020 18:35:40

US3532063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'I'	System	22 Aug 2020 18:35:40

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' User entered 'Yes (Y)'	System	18 Aug 2020 19:21:56
	System	18 Aug 2020 19:21:56

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' User entered '97.5'	System	18 Aug 2020 19:21:56
	System	18 Aug 2020 19:21:56

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' User entered 'No (N)'	System	18 Aug 2020 19:21:56
	System	18 Aug 2020 19:21:56

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:21:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '56dec1b9-4e6e-44c1-8552-48d9c3434436' User entered '18 Aug 2020 15:21'	System	18 Aug 2020 19:21:56
	System	18 Aug 2020 19:21:56

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 15:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 17:31'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:14:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' User entered 'Yes (Y)'	System	19 Aug 2020 01:15:43
	System	19 Aug 2020 01:15:43

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' User entered '96.8'	System	19 Aug 2020 01:15:43
	System	19 Aug 2020 01:15:43

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644'	System	19 Aug 2020 01:15:43
User entered 'No (N)'	System	19 Aug 2020 01:15:43

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b2614d4c-03bb-4402-b251-72569e616644' User entered '18 Aug 2020 21:15'	System	19 Aug 2020 01:15:43
	System	19 Aug 2020 01:15:43

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 18:26'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 2'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277'	System	20 Aug 2020 01:18:52
User entered 'Yes (Y)'	System	20 Aug 2020 01:18:52

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277'	System	20 Aug 2020 01:18:52
User entered '97.5'	System	20 Aug 2020 01:18:52

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277'	System	20 Aug 2020 01:18:52
User entered 'No (N)'	System	20 Aug 2020 01:18:52

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7e2327df-4234-44d9-a0c3-af249d3e3277'	System	20 Aug 2020 01:18:52
User entered '19 Aug 2020 21:18'	System	20 Aug 2020 01:18:52

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 3'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' User entered 'Yes (Y)'	System	21 Aug 2020 00:06:07
	System	21 Aug 2020 00:06:07

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' User entered '97.7'	System	21 Aug 2020 00:06:07
	System	21 Aug 2020 00:06:07

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:05:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' User entered 'No (N)'	System	21 Aug 2020 00:06:07
	System	21 Aug 2020 00:06:07

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '041b35b0-f674-4e13-9775-1645c837d90f' User entered '20 Aug 2020 20:06'	System	21 Aug 2020 00:06:07
	System	21 Aug 2020 00:06:07

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 4'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2' User entered 'Yes (Y)'	System	22 Aug 2020 02:02:57
	System	22 Aug 2020 02:02:57

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2' User entered '97.5'	System	22 Aug 2020 02:02:57
	System	22 Aug 2020 02:02:57

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2'	System	22 Aug 2020 02:02:57
User entered 'No (N)'	System	22 Aug 2020 02:02:57

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:02:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8d668f3d-0f67-4685-a30d-1d63eead02f2'	System	22 Aug 2020 02:02:57
User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:57

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 5'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:26:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' User entered 'Yes (Y)'	System	23 Aug 2020 01:27:25
	System	23 Aug 2020 01:27:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' User entered '96.2'	System	23 Aug 2020 01:27:25
	System	23 Aug 2020 01:27:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:17', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' User entered 'No (N)'	System	23 Aug 2020 01:27:25
	System	23 Aug 2020 01:27:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'eb05bc54-a303-47e7-a8c4-39f482e7439f' User entered '22 Aug 2020 21:27'	System	23 Aug 2020 01:27:25
	System	23 Aug 2020 01:27:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 6'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' User entered 'Yes (Y)'	System	24 Aug 2020 01:28:42
	System	24 Aug 2020 01:28:42

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:20', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' User entered '96.7'	System	24 Aug 2020 01:28:42
	System	24 Aug 2020 01:28:42

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258'	System	24 Aug 2020 01:28:42
User entered 'No (N)'	System	24 Aug 2020 01:28:42

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a4994578-ba70-47bc-ae12-bc9f70386258' User entered '23 Aug 2020 21:28'	System	24 Aug 2020 01:28:42
	System	24 Aug 2020 01:28:42

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 7'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' User entered 'Yes (Y)'	System	25 Aug 2020 05:15:04
	System	25 Aug 2020 05:15:04

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' User entered '96.8'	System	25 Aug 2020 05:15:04
	System	25 Aug 2020 05:15:04

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:14:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739'	System	25 Aug 2020 05:15:04
User entered 'No (N)'	System	25 Aug 2020 05:15:04

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '93bf4a70-d818-41d0-b7bc-7b5a449e6739' User entered '25 Aug 2020 01:15'	System	25 Aug 2020 05:15:04
	System	25 Aug 2020 05:15:04

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770'	System	18 Aug 2020 19:23:03
User entered 'None (1)'	System	18 Aug 2020 19:23:03

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770'	System	18 Aug 2020 19:23:03
User entered 'No (N)'	System	18 Aug 2020 19:23:03

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770'	System	18 Aug 2020 19:23:03
User entered 'No (N)'	System	18 Aug 2020 19:23:03

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770'	System	18 Aug 2020 19:23:03
User entered 'None (1)'	System	18 Aug 2020 19:23:03

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3564b664-7c04-4309-8604-0ec030e0b770' User entered '18 Aug 2020 15:22'	System	18 Aug 2020 19:23:03
	System	18 Aug 2020 19:23:03

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 15:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 17:31'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:15:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8'	System	19 Aug 2020 01:16:58
User entered 'None (1)'	System	19 Aug 2020 01:16:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' User entered 'No (N)'	System	19 Aug 2020 01:16:58
	System	19 Aug 2020 01:16:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' User entered 'No (N)'	System	19 Aug 2020 01:16:58
	System	19 Aug 2020 01:16:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8'	System	19 Aug 2020 01:16:58
User entered 'None (1)'	System	19 Aug 2020 01:16:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:16:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd16d7c2b-dbd1-4a0c-9a02-33deb4cb44d8' User entered '18 Aug 2020 21:16'	System	19 Aug 2020 01:16:58
	System	19 Aug 2020 01:16:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 18:26'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 2'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:18:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' User entered 'None (1)'	System	20 Aug 2020 01:19:51
	System	20 Aug 2020 01:19:51

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' User entered 'No (N)'	System	20 Aug 2020 01:19:51
	System	20 Aug 2020 01:19:51

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:34', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' User entered 'No (N)'	System	20 Aug 2020 01:19:51
	System	20 Aug 2020 01:19:51

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' User entered 'None (1)'	System	20 Aug 2020 01:19:51
	System	20 Aug 2020 01:19:51

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9e31483d-0892-4e15-b862-6d050a627f1c' User entered '19 Aug 2020 21:19'	System	20 Aug 2020 01:19:51
	System	20 Aug 2020 01:19:51

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 3'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:24', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' User entered 'None (1)'	System	21 Aug 2020 00:08:38
	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:17', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617'	System	21 Aug 2020 00:08:38
User entered 'No (N)'	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:06:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' User entered 'Yes (Y)'	System	21 Aug 2020 00:08:38
	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:07:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617' User entered '8'	System	21 Aug 2020 00:08:38
	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617'	System	21 Aug 2020 00:08:38
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '82705051-cf35-44b1-b648-3466e6be7617'	System	21 Aug 2020 00:08:38
User entered '20 Aug 2020 20:08'	System	21 Aug 2020 00:08:38

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 4'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' User entered 'None (1)'	System	22 Aug 2020 02:04:28
	System	22 Aug 2020 02:04:28

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' User entered 'No (N)'	System	22 Aug 2020 02:04:28
	System	22 Aug 2020 02:04:28

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' User entered 'No (N)'	System	22 Aug 2020 02:04:28
	System	22 Aug 2020 02:04:28

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' User entered 'None (1)'	System	22 Aug 2020 02:04:28
	System	22 Aug 2020 02:04:28

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f7a768c-7576-4589-bf41-3af83c7518fc' User entered '21 Aug 2020 22:04'	System	22 Aug 2020 02:04:28
	System	22 Aug 2020 02:04:28

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 5'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' User entered 'None (1)'	System	23 Aug 2020 01:28:53
	System	23 Aug 2020 01:28:53

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:27:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' User entered 'No (N)'	System	23 Aug 2020 01:28:53
	System	23 Aug 2020 01:28:53

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' User entered 'No (N)'	System	23 Aug 2020 01:28:53
	System	23 Aug 2020 01:28:53

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' User entered 'None (1)'	System	23 Aug 2020 01:28:53
	System	23 Aug 2020 01:28:53

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '989a15ea-8495-4a30-8b57-c4dab7041369' User entered '22 Aug 2020 21:28'	System	23 Aug 2020 01:28:53
	System	23 Aug 2020 01:28:53

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 6'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12'	System	24 Aug 2020 01:29:58
User entered 'None (1)'	System	24 Aug 2020 01:29:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12'	System	24 Aug 2020 01:29:58
User entered 'No (N)'	System	24 Aug 2020 01:29:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12'	System	24 Aug 2020 01:29:58
User entered 'No (N)'	System	24 Aug 2020 01:29:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12'	System	24 Aug 2020 01:29:58
User entered 'None (1)'	System	24 Aug 2020 01:29:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:28:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'abf08935-e688-4e27-af1f-644ba6c22a12'	System	24 Aug 2020 01:29:58
User entered '23 Aug 2020 21:28'	System	24 Aug 2020 01:29:58

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 7'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7'	System	25 Aug 2020 05:15:25
User entered 'None (1)'	System	25 Aug 2020 05:15:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7'	System	25 Aug 2020 05:15:25
User entered 'No (N)'	System	25 Aug 2020 05:15:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7'	System	25 Aug 2020 05:15:25
User entered 'No (N)'	System	25 Aug 2020 05:15:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7'	System	25 Aug 2020 05:15:25
User entered 'None (1)'	System	25 Aug 2020 05:15:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'da13109b-245b-4d22-bc02-e84f0dcfec7' User entered '25 Aug 2020 01:15'	System	25 Aug 2020 05:15:25
	System	25 Aug 2020 05:15:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:22:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered 'None (0)'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221'	System	18 Aug 2020 19:23:21
User entered 'No (N)'	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T15:23:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd187a012-952c-4028-b779-7e6d68218221' User entered '18 Aug 2020 15:23'	System	18 Aug 2020 19:23:21
	System	18 Aug 2020 19:23:21

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 15:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 17:31'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f'	System	19 Aug 2020 01:17:48
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered 'None (0)'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f'	System	19 Aug 2020 01:17:48
User entered 'No (N)'	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-18T21:17:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c8f48881-6bf6-40ba-bdc1-6653557fae2f' User entered '18 Aug 2020 21:17'	System	19 Aug 2020 01:17:48
	System	19 Aug 2020 01:17:48

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Aug 2020 18:26'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 2'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:19:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9'	System	20 Aug 2020 01:20:30
User entered 'No interference with activity (1)'	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'None (0)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered 'No (N)'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-19T21:20:27', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7723f06e-6935-4032-bfdb-313ed6d626e9' User entered '19 Aug 2020 21:20'	System	20 Aug 2020 01:20:30
	System	20 Aug 2020 01:20:30

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 3'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered 'None (0)'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e'	System	21 Aug 2020 00:09:12
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered 'None (0)'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered 'None (0)'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered 'None (0)'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:08:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered 'None (0)'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:09:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e'	System	21 Aug 2020 00:09:12
User entered 'No (N)'	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-20T20:09:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e267970-b6fb-4f96-b32a-c499d1d20e9e' User entered '20 Aug 2020 20:09'	System	21 Aug 2020 00:09:12
	System	21 Aug 2020 00:09:12

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 4'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'None (0)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:04:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered 'No (N)'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-21T22:05:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '8573475a-e26d-4b64-a2f0-e2e5a96f05d1' User entered '21 Aug 2020 22:05'	System	22 Aug 2020 02:05:05
	System	22 Aug 2020 02:05:05

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 5'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered 'None (0)'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633'	System	23 Aug 2020 01:29:14
User entered 'None (0)'	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:28:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered 'None (0)'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered 'None (0)'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:03', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered 'None (0)'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered 'None (0)'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633'	System	23 Aug 2020 01:29:14
User entered 'No (N)'	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-22T21:29:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bcb8460d-7d30-4600-b653-1ec7c19ce633' User entered '22 Aug 2020 21:29'	System	23 Aug 2020 01:29:14
	System	23 Aug 2020 01:29:14

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 6'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2'	System	24 Aug 2020 01:30:15
User entered 'None (0)'	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2'	System	24 Aug 2020 01:30:15
User entered 'No interference with activity (1)'	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' User entered 'None (0)'	System	24 Aug 2020 01:30:15
	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' User entered 'None (0)'	System	24 Aug 2020 01:30:15
	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' User entered 'None (0)'	System	24 Aug 2020 01:30:15
	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:18', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' User entered 'None (0)'	System	24 Aug 2020 01:30:15
	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2'	System	24 Aug 2020 01:30:15
User entered 'No (N)'	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-23T21:29:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b7e9aa5c-8bfa-42ab-a9a8-3ac61f17b4e2' User entered '23 Aug 2020 21:29'	System	24 Aug 2020 01:30:15
	System	24 Aug 2020 01:30:15

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 7'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'None (0)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered 'No (N)'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-08-25T01:15:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'bde57e46-b4f1-432d-84a6-6d268540e75f' User entered '25 Aug 2020 01:15'	System	25 Aug 2020 05:15:52
	System	25 Aug 2020 05:15:52

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:58:25

US3532063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	26 Aug 2020 17:55:58

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '26 Aug 2020'	Kathy Stephens (b) (4)	26 Aug 2020 17:55:58

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	26 Aug 2020 17:55:58

US3532063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:55:58

US3532063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:56:04

US3532063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	26 Aug 2020 17:56:04

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Sep 2020 01:40:43

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '2 Sep 2020'	(b) (4) Kathy Stephens (b) (4) (b) (4)	03 Sep 2020 01:40:43

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4)	03 Sep 2020 01:40:43

US3532063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	03 Sep 2020 01:40:43

US3532063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Sep 2020 01:40:47

US3532063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	03 Sep 2020 01:40:47

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	10 Sep 2020 22:03:54

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '10 Sep 2020'	Kathy Stephens (b) (4)	10 Sep 2020 22:03:54

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4)	10 Sep 2020 22:03:54

US3532063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	10 Sep 2020 22:03:54

US3532063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	10 Sep 2020 22:04:05

US3532063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	10 Sep 2020 22:04:05

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 18:40:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	Kathy Stephens (b) (4)	16 Sep 2020 18:40:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	16 Sep 2020 18:40:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'VISIT2'	System	16 Sep 2020 18:40:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User accepted default value 'Pre-Dose (PREDOSE)'	Kathy Stephens (b) (4) (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:09'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '16 Sep 2020 14:09'	System	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '98.3' F	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Oral (Oral)'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '73'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'bpm'	System	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'breaths/min'	System	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '105'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '63'	Kathy Stephens (b) (4)	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	16 Sep 2020 19:00:16

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User accepted default value 'Post-Dose (POSTDOSE)'	Kathy Stephens (b) (4) (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '15:43'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '16 Sep 2020 15:43'	System	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '97.9' F	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '66'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'bpm'	System	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'breaths/min'	System	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '109'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '67'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	16 Sep 2020 23:37:12

US3532063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 18:40:25

US3532063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	Kathy Stephens (b) (4)	16 Sep 2020 18:40:25

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '15:11'	Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '16 Sep 2020 15:11'	System	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Left Arm (LEFT ARM)'	Kathy Stephens (b) (4)	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'ONCE'	System	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 19:20:23

US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 18:58:44

US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 18:58:44

US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:50'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 18:58:44

US3532063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '16 Sep 2020 14:50'	System	16 Sep 2020 18:58:44

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '16 Sep 2020'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kathy Stephens (b) (4) (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14:37'	Kathy Stephens (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '16 Sep 2020 14:37'	System	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kathy Stephens (b) (4) (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	(b) (4) Kathy Stephens (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered empty.	System	16 Sep 2020 18:59:08

US3532063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Sep 2020 23:37:20

US3532063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	16 Sep 2020 23:37:20

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' User entered 'Yes (Y)'	System	16 Sep 2020 19:43:58
	System	16 Sep 2020 19:43:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' User entered '97.9'	System	16 Sep 2020 19:43:58
	System	16 Sep 2020 19:43:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed'	System	16 Sep 2020 19:43:58
User entered 'No (N)'	System	16 Sep 2020 19:43:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:43:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '78ade3f6-a2ff-46b1-8297-328c79be2bed' User entered '16 Sep 2020 15:43'	System	16 Sep 2020 19:43:58
	System	16 Sep 2020 19:43:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:01'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' User entered 'Yes (Y)'	System	17 Sep 2020 01:22:57
	System	17 Sep 2020 01:22:57

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' User entered '97.5'	System	17 Sep 2020 01:22:57
	System	17 Sep 2020 01:22:57

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' User entered 'No (N)'	System	17 Sep 2020 01:22:57
	System	17 Sep 2020 01:22:57

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cc16f35a-cbb6-4f34-8cd4-26efdf1d3484' User entered '16 Sep 2020 21:21'	System	17 Sep 2020 01:22:57
	System	17 Sep 2020 01:22:57

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:56'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 2'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' User entered 'Yes (Y)'	System	18 Sep 2020 01:49:58
	System	18 Sep 2020 01:49:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0' User entered '96.5'	System	18 Sep 2020 01:49:58
	System	18 Sep 2020 01:49:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0'	System	18 Sep 2020 01:49:58
User entered 'No (N)'	System	18 Sep 2020 01:49:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:49:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b42452d4-f21c-4c1f-9821-0eb7bbf95df0'	System	18 Sep 2020 01:49:58
User entered '17 Sep 2020 21:49'	System	18 Sep 2020 01:49:58

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 3'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d'	System	19 Sep 2020 08:43:36
User entered 'Yes (Y)'	System	19 Sep 2020 08:43:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' User entered '96.5'	System	19 Sep 2020 08:43:36
	System	19 Sep 2020 08:43:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d'	System	19 Sep 2020 08:43:36
User entered 'No (N)'	System	19 Sep 2020 08:43:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:34', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'efbb6ef5-7bf5-41c6-9d80-ec760d1b514d' User entered '19 Sep 2020 04:43'	System	19 Sep 2020 08:43:36
	System	19 Sep 2020 08:43:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 4'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' User entered 'Yes (Y)'	System	20 Sep 2020 00:59:45
	System	20 Sep 2020 00:59:45

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' User entered '95.4'	System	20 Sep 2020 00:59:45
	System	20 Sep 2020 00:59:45

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7'	System	20 Sep 2020 00:59:45
User entered 'No (N)'	System	20 Sep 2020 00:59:45

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T20:59:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '816adde5-117f-45cf-b886-96d0a8c3e5c7' User entered '19 Sep 2020 20:59'	System	20 Sep 2020 00:59:45
	System	20 Sep 2020 00:59:45

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 5'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' User entered 'Yes (Y)'	System	21 Sep 2020 01:06:48
	System	21 Sep 2020 01:06:48

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' User entered '96.4'	System	21 Sep 2020 01:06:48
	System	21 Sep 2020 01:06:48

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' User entered 'No (N)'	System	21 Sep 2020 01:06:48
	System	21 Sep 2020 01:06:48

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:06:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '801b6404-4437-4d0b-aace-655ed53328bb' User entered '20 Sep 2020 21:06'	System	21 Sep 2020 01:06:48
	System	21 Sep 2020 01:06:48

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 6'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' User entered 'Yes (Y)'	System	22 Sep 2020 01:21:02
	System	22 Sep 2020 01:21:02

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' User entered '97.1'	System	22 Sep 2020 01:21:02
	System	22 Sep 2020 01:21:02

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' User entered 'No (N)'	System	22 Sep 2020 01:21:02
	System	22 Sep 2020 01:21:02

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:20:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '24626056-0746-4047-8bce-e8aaf591674b' User entered '21 Sep 2020 21:20'	System	22 Sep 2020 01:21:02
	System	22 Sep 2020 01:21:02

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 7'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:01:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' User entered 'Yes (Y)'	System	23 Sep 2020 01:02:36
	System	23 Sep 2020 01:02:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6' User entered '97.1'	System	23 Sep 2020 01:02:36
	System	23 Sep 2020 01:02:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6'	System	23 Sep 2020 01:02:36
User entered 'No (N)'	System	23 Sep 2020 01:02:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '07db9866-378f-4506-aa7c-2cf3f0c69dc6'	System	23 Sep 2020 01:02:36
User entered '22 Sep 2020 21:02'	System	23 Sep 2020 01:02:36

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' User entered 'None (1)'	System	16 Sep 2020 19:44:42
	System	16 Sep 2020 19:44:42

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' User entered 'No (N)'	System	16 Sep 2020 19:44:42
	System	16 Sep 2020 19:44:42

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' User entered 'No (N)'	System	16 Sep 2020 19:44:42
	System	16 Sep 2020 19:44:42

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' User entered 'None (1)'	System	16 Sep 2020 19:44:42
	System	16 Sep 2020 19:44:42

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cfd28096-adf7-46b7-bac6-415654e56509' User entered '16 Sep 2020 15:44'	System	16 Sep 2020 19:44:42
	System	16 Sep 2020 19:44:42

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:01'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:21:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'None (1)'	System	17 Sep 2020 01:23:47
	System	17 Sep 2020 01:23:47

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:20', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'No (N)'	System	17 Sep 2020 01:23:47
	System	17 Sep 2020 01:23:47

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'No (N)'	System	17 Sep 2020 01:23:47
	System	17 Sep 2020 01:23:47

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered 'None (1)'	System	17 Sep 2020 01:23:47
	System	17 Sep 2020 01:23:47

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1a7339d-b0b2-44c8-a054-eb01a5fb00be' User entered '16 Sep 2020 21:22'	System	17 Sep 2020 01:23:47
	System	17 Sep 2020 01:23:47

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:56'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 2'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:50:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75'	System	18 Sep 2020 01:52:15
User entered 'None (1)'	System	18 Sep 2020 01:52:15

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75'	System	18 Sep 2020 01:52:15
User entered 'No (N)'	System	18 Sep 2020 01:52:15

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75'	System	18 Sep 2020 01:52:15
User entered 'No (N)'	System	18 Sep 2020 01:52:15

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75'	System	18 Sep 2020 01:52:15
User entered 'None (1)'	System	18 Sep 2020 01:52:15

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:51:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '03a4a3b2-a293-4d0c-9255-b2262e862c75' User entered '17 Sep 2020 21:51'	System	18 Sep 2020 01:52:15
	System	18 Sep 2020 01:52:15

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 3'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e'	System	19 Sep 2020 08:44:04
User entered 'None (1)'	System	19 Sep 2020 08:44:04

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' User entered 'No (N)'	System	19 Sep 2020 08:44:04
	System	19 Sep 2020 08:44:04

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' User entered 'No (N)'	System	19 Sep 2020 08:44:04
	System	19 Sep 2020 08:44:04

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:43:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' User entered 'None (1)'	System	19 Sep 2020 08:44:04
	System	19 Sep 2020 08:44:04

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '1f776142-da5c-4ede-b3fa-7c2700e7100e' User entered '19 Sep 2020 04:44'	System	19 Sep 2020 08:44:04
	System	19 Sep 2020 08:44:04

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 4'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered 'None (1)'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered 'No (N)'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:00:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered 'Yes (Y)'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered '300'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered 'None (1)'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:27', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '81a2866d-b72d-4a40-864a-5bea5f5c64ce' User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 5'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:07:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5'	System	21 Sep 2020 01:08:12
User entered 'None (1)'	System	21 Sep 2020 01:08:12

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:07:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5'	System	21 Sep 2020 01:08:12
User entered 'No (N)'	System	21 Sep 2020 01:08:12

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5'	System	21 Sep 2020 01:08:12
User entered 'No (N)'	System	21 Sep 2020 01:08:12

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5'	System	21 Sep 2020 01:08:12
User entered 'None (1)'	System	21 Sep 2020 01:08:12

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92b38ef-5139-4b96-b6b6-aaf0c87807f5'	System	21 Sep 2020 01:08:12
User entered '20 Sep 2020 21:08'	System	21 Sep 2020 01:08:12

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 6'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75'	System	22 Sep 2020 01:22:30
User entered 'None (1)'	System	22 Sep 2020 01:22:30

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75'	System	22 Sep 2020 01:22:30
User entered 'No (N)'	System	22 Sep 2020 01:22:30

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75' User entered 'No (N)'	System	22 Sep 2020 01:22:30
	System	22 Sep 2020 01:22:30

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75'	System	22 Sep 2020 01:22:30
User entered 'None (1)'	System	22 Sep 2020 01:22:30

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '929d747c-1524-491f-9015-caab30337c75'	System	22 Sep 2020 01:22:30
User entered '21 Sep 2020 21:22'	System	22 Sep 2020 01:22:30

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 7'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949'	System	23 Sep 2020 01:02:55
User entered 'None (1)'	System	23 Sep 2020 01:02:55

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949'	System	23 Sep 2020 01:02:55
User entered 'No (N)'	System	23 Sep 2020 01:02:55

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:42', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949' User entered 'No (N)'	System	23 Sep 2020 01:02:55
	System	23 Sep 2020 01:02:55

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:49', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949'	System	23 Sep 2020 01:02:55
User entered 'None (1)'	System	23 Sep 2020 01:02:55

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a8290410-03f4-42ff-a898-f5df41a09949'	System	23 Sep 2020 01:02:55
User entered '22 Sep 2020 21:02'	System	23 Sep 2020 01:02:55

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:52', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:44:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:08', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'None (0)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered 'No (N)'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T15:45:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e380d05-0ba1-46bb-830d-d798035b48e6' User entered '16 Sep 2020 15:45'	System	16 Sep 2020 19:45:16
	System	16 Sep 2020 19:45:16

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:01'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:45', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:54', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:22:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered 'None (0)'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:04', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860'	System	17 Sep 2020 01:23:57
User entered 'No (N)'	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-16T21:23:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b870c7b3-be62-441c-8d66-48a77d0c6860' User entered '16 Sep 2020 21:23'	System	17 Sep 2020 01:23:57
	System	17 Sep 2020 01:23:57

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '16 Sep 2020 18:56'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 2'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc'	System	18 Sep 2020 01:52:32
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:07', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc'	System	18 Sep 2020 01:52:32
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'None (0)'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered 'No (N)'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-17T21:52:28', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6945ac54-1c96-437a-bd1e-c436c21309dc' User entered '17 Sep 2020 21:52'	System	18 Sep 2020 01:52:32
	System	18 Sep 2020 01:52:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 3'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'None (0)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered 'No (N)'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T04:44:30', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e20019b9-ceb6-47e1-9407-fa8a0cf56f3d' User entered '19 Sep 2020 04:44'	System	19 Sep 2020 08:44:32
	System	19 Sep 2020 08:44:32

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 4'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265'	System	20 Sep 2020 01:02:54
User entered 'None (0)'	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265'	System	20 Sep 2020 01:02:54
User entered 'None (0)'	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:36', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' User entered 'None (0)'	System	20 Sep 2020 01:02:54
	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' User entered 'None (0)'	System	20 Sep 2020 01:02:54
	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:41', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' User entered 'None (0)'	System	20 Sep 2020 01:02:54
	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265'	System	20 Sep 2020 01:02:54
User entered 'None (0)'	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265'	System	20 Sep 2020 01:02:54
User entered 'No (N)'	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-19T21:02:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'baa9ff98-3eac-45f4-b48f-596b0f25a265' User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:54
	System	20 Sep 2020 01:02:54

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 5'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:15', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:18', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'None (0)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered 'No (N)'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-20T21:08:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ee003044-3da1-4211-814c-7d99ad4b3df5' User entered '20 Sep 2020 21:08'	System	21 Sep 2020 01:08:39
	System	21 Sep 2020 01:08:39

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 6'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:31', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:38', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'None (0)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered 'No (N)'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-21T21:22:49', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '961afd1e-60a3-4d45-90f0-f070a89bf241' User entered '21 Sep 2020 21:22'	System	22 Sep 2020 01:22:50
	System	22 Sep 2020 01:22:50

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	16 Sep 2020 19:20:23
User entered 'Day 7'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:02:57', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered 'None (0)'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered 'None (0)'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered 'None (0)'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered 'None (0)'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66'	System	23 Sep 2020 01:03:22
User entered 'None (0)'	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered 'None (0)'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66'	System	23 Sep 2020 01:03:22
User entered 'No (N)'	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-09-22T21:03:19', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e237a03d-e2a7-4b45-9155-71865cf6ff66' User entered '22 Sep 2020 21:03'	System	23 Sep 2020 01:03:22
	System	23 Sep 2020 01:03:22

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:20:23

US3532063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:20:23

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Sep 2020 20:31:05

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered '26 Sep 2020'	Kathy Stephens (b) (4)	26 Sep 2020 20:31:05

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4)	26 Sep 2020 20:31:05

US3532063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered empty.	Kathy Stephens (b) (4)	26 Sep 2020 20:31:05

US3532063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 10:54:21
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Sep 2020 20:31:11

US3532063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	26 Sep 2020 20:31:11

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Oct 2020 21:25:30

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '3 Oct 2020'	Kathy Stephens (b) (4)	03 Oct 2020 21:25:30

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4)	03 Oct 2020 21:25:30

US3532063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	03 Oct 2020 21:25:30

US3532063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Oct 2020 21:25:36

US3532063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	03 Oct 2020 21:25:36

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	14 Oct 2020 17:43:38

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '10 Oct 2020'	Kathy Stephens (b) (4)	14 Oct 2020 17:43:38

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4)	14 Oct 2020 17:43:38

US3532063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	(b) (4) Kathy Stephens (b) (4)	14 Oct 2020 17:43:38

US3532063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	14 Oct 2020 17:43:44

US3532063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'I'	System	14 Oct 2020 17:43:44

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	14 Oct 2020 18:02:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14 Oct 2020'	Kathy Stephens (b) (4)	14 Oct 2020 18:02:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	14 Oct 2020 18:02:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'VISIT3'	System	14 Oct 2020 18:02:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14 Oct 2020'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '13:36'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '14 Oct 2020 13:36'	System	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '97.9' F	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '65'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'bpm'	System	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'breaths/min'	System	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '113'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '74'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered 'mmHg'	System	14 Oct 2020 18:03:11

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17

US3532063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17

US3532063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'No (N)'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:16

US3532063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered empty.	Kathy Stephens (b) (4)	14 Oct 2020 18:03:16

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:45

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '14 Oct 2020'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:45

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered '13:54'	(b) (4) Kathy Stephens (b) (4)	14 Oct 2020 18:03:45

US3532063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '14 Oct 2020 13:54'	System	14 Oct 2020 18:03:45

US3532063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:06:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	14 Oct 2020 18:03:49

US3532063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:33:17
User entered '1'	System	14 Oct 2020 18:03:49

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 64'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:03:53', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9' User entered 'No (N)'	System	18 Oct 2020 16:04:18
	System	18 Oct 2020 16:04:18

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:03:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9'	System	18 Oct 2020 16:04:18
User entered 'No (N)'	System	18 Oct 2020 16:04:18

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-18T12:04:16', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'e1968fb9-8231-4dcd-97c6-2a1c499b7ab9' User entered '18 Oct 2020 12:04:16'	System	18 Oct 2020 16:04:18
	System	18 Oct 2020 16:04:18

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 71'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9' User entered 'No (N)'	System	25 Oct 2020 11:40:03
	System	25 Oct 2020 11:40:03

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9'	System	25 Oct 2020 11:40:03
User entered 'No (N)'	System	25 Oct 2020 11:40:03

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-10-25T07:39:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '7c544880-5d79-4f1d-8173-a40465d757b9' User entered '25 Oct 2020 07:39:59'	System	25 Oct 2020 11:40:03
	System	25 Oct 2020 11:40:03

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 78'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered 'Yes (Y)'	System	03 Nov 2020 00:10:32
	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:46', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered 'No (N)'	System	03 Nov 2020 00:10:32
	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:09:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd'	System	03 Nov 2020 00:10:32
User entered 'No (N)'	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered 'Yes (Y)'	System	03 Nov 2020 00:10:32
	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Please 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)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:11', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd'	System	03 Nov 2020 00:10:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-02T18:10:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cf34177f-e585-4aa8-bf15-43151f6c03cd' User entered '02 Nov 2020 18:10:23'	System	03 Nov 2020 00:10:32
	System	03 Nov 2020 00:10:32

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered 'Day 92'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:13', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' User entered 'No (N)'	System	15 Nov 2020 13:23:39
	System	15 Nov 2020 13:23:39

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' User entered 'No (N)'	System	15 Nov 2020 13:23:39
	System	15 Nov 2020 13:23:39

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-15T07:23:35', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'ab81e6c5-7928-4cf7-a167-8b73a126f6f3' User entered '15 Nov 2020 07:23:35'	System	15 Nov 2020 13:23:39
	System	15 Nov 2020 13:23:39

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 18:58:25

US3532063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:05:58
Data entry locked.	System	18 Aug 2020 18:58:25
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 18:58:25

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:23:43', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered 'No (N)'	System	21 Nov 2020 20:24:15
	System	21 Nov 2020 20:24:15

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:24:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered 'No (N)'	System	21 Nov 2020 20:24:15

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-21T14:24:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '2e93d0f2-ff6a-4b4f-b98f-ae533dd17a9e' User entered '21 Nov 2020 14:24:12'	System	21 Nov 2020 20:24:15
	System	21 Nov 2020 20:24:15

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-26T00:22:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9367198b-6ee2-4b4f-9723-8785445e17f0'	System	26 Nov 2020 06:22:38
User entered 'No (N)'	System	26 Nov 2020 06:22:38

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-26T00:22:26', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9367198b-6ee2-4b4f-9723-8785445e17f0'	System	26 Nov 2020 06:22:38
User entered 'No (N)'	System	26 Nov 2020 06:22:38

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-11-26T00:22:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '9367198b-6ee2-4b4f-9723-8785445e17f0' User entered '26 Nov 2020 00:22:33'	System	26 Nov 2020 06:22:38
	System	26 Nov 2020 06:22:38

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-03T06:11:06', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '324064d5-cef6-401b-9de0-b9f902f0ab93'	System	03 Dec 2020 12:11:24
User entered 'No (N)'	System	03 Dec 2020 12:11:24

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-03T06:11:12', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '324064d5-cef6-401b-9de0-b9f902f0ab93'	System	03 Dec 2020 12:11:24
User entered 'No (N)'	System	03 Dec 2020 12:11:24

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-03T06:11:22', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '324064d5-cef6-401b-9de0-b9f902f0ab93' User entered '03 Dec 2020 06:11:22'	System	03 Dec 2020 12:11:24
	System	03 Dec 2020 12:11:24

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-10T06:00:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3ff431bd-b9c5-4531-aa3c-fbc172005f02'	System	10 Dec 2020 12:00:52
User entered 'No (N)'	System	10 Dec 2020 12:00:52

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-10T06:00:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3ff431bd-b9c5-4531-aa3c-fbc172005f02'	System	10 Dec 2020 12:00:52
User entered 'No (N)'	System	10 Dec 2020 12:00:52

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-10T06:00:47', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '3ff431bd-b9c5-4531-aa3c-fbc172005f02' User entered '10 Dec 2020 06:00:47'	System	10 Dec 2020 12:00:52
	System	10 Dec 2020 12:00:52

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-17T13:36:10', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd55aef74-cad0-48ca-8558-d7a19c520e7d' User entered 'No (N)'	System	17 Dec 2020 18:36:20
	System	17 Dec 2020 18:36:20

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-17T13:36:14', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd55aef74-cad0-48ca-8558-d7a19c520e7d' User entered 'No (N)'	System	17 Dec 2020 18:36:20
	System	17 Dec 2020 18:36:20

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-17T13:36:18', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd55aef74-cad0-48ca-8558-d7a19c520e7d' User entered '17 Dec 2020 13:36:18'	System	17 Dec 2020 18:36:20
	System	17 Dec 2020 18:36:20

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-27T13:10:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92348d8-ef63-4b8c-9883-ecd7b777db7c' User entered 'No (N)'	System	27 Dec 2020 18:10:42
	System	27 Dec 2020 18:10:42

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-27T13:10:37', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92348d8-ef63-4b8c-9883-ecd7b777db7c' User entered 'No (N)'	System	27 Dec 2020 18:10:42
	System	27 Dec 2020 18:10:42

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-27T13:10:40', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c92348d8-ef63-4b8c-9883-ecd7b777db7c' User entered '27 Dec 2020 13:10:40'	System	27 Dec 2020 18:10:42
	System	27 Dec 2020 18:10:42

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-31T06:28:33', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aee68c4c-e8bb-4bcf-86b5-7f36d5309e3f' User entered 'No (N)'	System	31 Dec 2020 11:28:49
	System	31 Dec 2020 11:28:49

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-31T06:28:39', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aee68c4c-e8bb-4bcf-86b5-7f36d5309e3f' User entered 'No (N)'	System	31 Dec 2020 11:28:49
	System	31 Dec 2020 11:28:49

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2020-12-31T06:28:44', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aee68c4c-e8bb-4bcf-86b5-7f36d5309e3f' User entered '31 Dec 2020 06:28:44'	System	31 Dec 2020 11:28:49

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-07T05:48:51', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '5a0dda12-92f5-4d1a-8a74-3b37e0698cfe' User entered 'No (N)'	System	07 Jan 2021 10:49:02

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-07T05:48:56', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '5a0dda12-92f5-4d1a-8a74-3b37e0698cfe' User entered 'No (N)'	System	07 Jan 2021 10:49:02

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-07T05:49:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '5a0dda12-92f5-4d1a-8a74-3b37e0698cfe' User entered '07 Jan 2021 05:49:00'	System	07 Jan 2021 10:49:02
	System	07 Jan 2021 10:49:02

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-14T21:21:48', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '4e9e0b74-6d2e-43af-a81b-f410ab037302'	System	15 Jan 2021 02:22:06
User entered 'No (N)'	System	15 Jan 2021 02:22:06

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-14T21:21:50', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '4e9e0b74-6d2e-43af-a81b-f410ab037302'	System	15 Jan 2021 02:22:06
User entered 'No (N)'	System	15 Jan 2021 02:22:06

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-14T21:22:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '4e9e0b74-6d2e-43af-a81b-f410ab037302' User entered '14 Jan 2021 21:22:02'	System	15 Jan 2021 02:22:06
	System	15 Jan 2021 02:22:06

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-21T12:23:21', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '44000a19-4dee-44ef-b360-20d398dddd18' User entered 'No (N)'	System	21 Jan 2021 17:23:32
	System	21 Jan 2021 17:23:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-21T12:23:25', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '44000a19-4dee-44ef-b360-20d398dddd18' User entered 'No (N)'	System	21 Jan 2021 17:23:32
	System	21 Jan 2021 17:23:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-21T12:23:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '44000a19-4dee-44ef-b360-20d398dddd18' User entered '21 Jan 2021 12:23:29'	System	21 Jan 2021 17:23:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-28T06:03:49', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '94e3bcbe-6116-430a-97c6-37d8843c261e' User entered 'No (N)'	System	28 Jan 2021 11:04:05
	System	28 Jan 2021 11:04:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-28T06:03:58', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '94e3bcbe-6116-430a-97c6-37d8843c261e' User entered 'No (N)'	System	28 Jan 2021 11:04:05
	System	28 Jan 2021 11:04:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-01-28T06:04:01', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '94e3bcbe-6116-430a-97c6-37d8843c261e' User entered '28 Jan 2021 06:04:01'	System	28 Jan 2021 11:04:05
	System	28 Jan 2021 11:04:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-04T06:26:23', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b419aa45-85d7-4363-ab4f-9489e5dfcc0e' User entered 'No (N)'	System	04 Feb 2021 11:26:36
	System	04 Feb 2021 11:26:36

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-04T06:26:29', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b419aa45-85d7-4363-ab4f-9489e5dfcc0e' User entered 'No (N)'	System	04 Feb 2021 11:26:36
	System	04 Feb 2021 11:26:36

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-04T06:26:32', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'b419aa45-85d7-4363-ab4f-9489e5dfcc0e' User entered '04 Feb 2021 06:26:32'	System	04 Feb 2021 11:26:36
	System	04 Feb 2021 11:26:36

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-11T09:17:55', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '259b558d-e7d3-4377-b496-1bfdca9f6de7'	System	11 Feb 2021 14:18:05
User entered 'No (N)'	System	11 Feb 2021 14:18:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-11T09:17:59', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '259b558d-e7d3-4377-b496-1bfdca9f6de7'	System	11 Feb 2021 14:18:05
User entered 'No (N)'	System	11 Feb 2021 14:18:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-11T09:18:02', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '259b558d-e7d3-4377-b496-1bfdca9f6de7' User entered '11 Feb 2021 09:18:02'	System	11 Feb 2021 14:18:05
	System	11 Feb 2021 14:18:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-19T12:21:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aeef09c2-e82a-49c6-92f7-38f529c1a046' User entered 'No (N)'	System	19 Feb 2021 17:23:17
	System	19 Feb 2021 17:23:17

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-19T12:21:05', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aeef09c2-e82a-49c6-92f7-38f529c1a046'	System	19 Feb 2021 17:23:17
User entered 'No (N)'	System	19 Feb 2021 17:23:17

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-19T12:21:09', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'aeef09c2-e82a-49c6-92f7-38f529c1a046' User entered '19 Feb 2021 12:21:09'	System	19 Feb 2021 17:23:17
	System	19 Feb 2021 17:23:17

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-25T06:59:23-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c630410d-0abb-4ba8-86b6-7b66306143eb' User entered 'No (N)'	System	25 Feb 2021 11:59:41
	System	25 Feb 2021 11:59:41

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-25T06:59:27-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c630410d-0abb-4ba8-86b6-7b66306143eb' User entered 'No (N)'	System	25 Feb 2021 11:59:41

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-02-25T06:59:36-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c630410d-0abb-4ba8-86b6-7b66306143eb' User entered '25 Feb 2021 11:59:36'	System	25 Feb 2021 11:59:41
	System	25 Feb 2021 11:59:41

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-04T06:17:17-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '16607dad-f79e-4639-ad39-5a11ba9be411'	System	04 Mar 2021 11:17:32
User entered 'No (N)'	System	04 Mar 2021 11:17:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-04T06:17:20-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '16607dad-f79e-4639-ad39-5a11ba9be411'	System	04 Mar 2021 11:17:32
User entered 'No (N)'	System	04 Mar 2021 11:17:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-04T06:17:29-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '16607dad-f79e-4639-ad39-5a11ba9be411' User entered '04 Mar 2021 06:17:29'	System	04 Mar 2021 11:17:32
	System	04 Mar 2021 11:17:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-11T08:24:47-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1bf2a09-9bcc-44d1-98f8-35fd5a880cdc' User entered 'No (N)'	System	11 Mar 2021 13:25:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-11T08:24:56-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1bf2a09-9bcc-44d1-98f8-35fd5a880cdc'	System	11 Mar 2021 13:25:05
User entered 'No (N)'	System	11 Mar 2021 13:25:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-11T08:25:01-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'c1bf2a09-9bcc-44d1-98f8-35fd5a880cdc' User entered '11 Mar 2021 08:25:01'	System	11 Mar 2021 13:25:05
	System	11 Mar 2021 13:25:05

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-18T04:59:27-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd2df8f2d-a775-46ab-b315-36b9b57d11aa'	System	18 Mar 2021 08:59:39
User entered 'No (N)'	System	18 Mar 2021 08:59:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-18T04:59:31-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd2df8f2d-a775-46ab-b315-36b9b57d11aa'	System	18 Mar 2021 08:59:39
User entered 'No (N)'	System	18 Mar 2021 08:59:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-18T04:59:36-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'd2df8f2d-a775-46ab-b315-36b9b57d11aa' User entered '18 Mar 2021 04:59:36'	System	18 Mar 2021 08:59:39
	System	18 Mar 2021 08:59:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-25T06:15:42-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6c4e5e35-606c-44f6-af1b-ca00ee5f918d' User entered 'No (N)'	System	25 Mar 2021 10:15:54
	System	25 Mar 2021 10:15:54

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-25T06:15:48-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6c4e5e35-606c-44f6-af1b-ca00ee5f918d' User entered 'No (N)'	System	25 Mar 2021 10:15:54

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-25T06:15:52-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '6c4e5e35-606c-44f6-af1b-ca00ee5f918d' User entered '25 Mar 2021 06:15:52'	System	25 Mar 2021 10:15:54
	System	25 Mar 2021 10:15:54

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-01T12:51:09-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '264fec55-e361-4956-9710-d3bf7d6b1a1c' User entered 'No (N)'	System	01 Apr 2021 16:51:21
	System	01 Apr 2021 16:51:21

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-01T12:51:14-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '264fec55-e361-4956-9710-d3bf7d6b1a1c'	System	01 Apr 2021 16:51:21
User entered 'No (N)'	System	01 Apr 2021 16:51:21

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-01T12:51:17-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '264fec55-e361-4956-9710-d3bf7d6b1a1c'	System	01 Apr 2021 16:51:21
User entered '01 Apr 2021 12:51:17'	System	01 Apr 2021 16:51:21

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-08T06:51:59-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a0a009c9-16ee-4eab-a840-ff4359908c75'	System	08 Apr 2021 10:52:39
User entered 'No (N)'	System	08 Apr 2021 10:52:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-08T06:52:01-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a0a009c9-16ee-4eab-a840-ff4359908c75'	System	08 Apr 2021 10:52:39
User entered 'No (N)'	System	08 Apr 2021 10:52:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-08T06:52:05-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'a0a009c9-16ee-4eab-a840-ff4359908c75'	System	08 Apr 2021 10:52:39
User entered '08 Apr 2021 06:52:05'	System	08 Apr 2021 10:52:39

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-15T12:21:53-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cd40a759-f345-453e-b85a-6e338658762b' User entered 'No (N)'	System	15 Apr 2021 16:22:10
	System	15 Apr 2021 16:22:10

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-15T12:22:00-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cd40a759-f345-453e-b85a-6e338658762b' User entered 'No (N)'	System	15 Apr 2021 16:22:10
	System	15 Apr 2021 16:22:10

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-15T12:22:03-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'cd40a759-f345-453e-b85a-6e338658762b' User entered '15 Apr 2021 12:22:03'	System	15 Apr 2021 16:22:10
	System	15 Apr 2021 16:22:10

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-22T07:05:36-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'fc4312a9-72e7-4ca7-ad82-f3320ed92398'	System	22 Apr 2021 11:05:48
User entered 'No (N)'	System	22 Apr 2021 11:05:48

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-22T07:05:41-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'fc4312a9-72e7-4ca7-ad82-f3320ed92398'	System	22 Apr 2021 11:05:48
User entered 'No (N)'	System	22 Apr 2021 11:05:48

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-22T07:05:45-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'fc4312a9-72e7-4ca7-ad82-f3320ed92398'	System	22 Apr 2021 11:05:48
User entered '22 Apr 2021 07:05:45'	System	22 Apr 2021 11:05:48

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-29T11:26:43-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '04c42120-2fa7-4b66-a039-05e28a0ffe58'	System	29 Apr 2021 18:01:32
User entered 'No (N)'	System	29 Apr 2021 18:01:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Have you been exposed to someone with 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 (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-29T11:26:47-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '04c42120-2fa7-4b66-a039-05e28a0ffe58'	System	29 Apr 2021 18:01:32
User entered 'No (N)'	System	29 Apr 2021 18:01:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-04-29T11:26:51-04:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: '04c42120-2fa7-4b66-a039-05e28a0ffe58'	System	29 Apr 2021 18:01:32
User entered '29 Apr 2021 11:26:51'	System	29 Apr 2021 18:01:32

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:22:31

US3532063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:22:31
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:22:31

US3532063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:08:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:05:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-01T21:33:58-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'f47f492f-8bfb-49b6-a785-cb33b08a783a'	System	02 Mar 2021 02:39:47
User entered 'No (N)'	System	02 Mar 2021 02:39:47

US3532063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:08:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:05:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D83D021-AB8C-4F81-B602-C2A1E0F66F4D)', Time: '2021-03-01T21:34:07-05:00', User OID: 'PatientReportedOutcome (US3532063)', ODM File OID: 'f47f492f-8bf6-49b6-a785-cb33b08a783a' User entered '01 Mar 2021 21:34:07'	System	02 Mar 2021 02:39:47
	System	02 Mar 2021 02:39:47

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:35:08
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	09 Nov 2020 18:22:01

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:35:08
User entered '9 Nov 2020'	Kathy Stephens (b) (4)	09 Nov 2020 18:22:01

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:35:08
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	09 Nov 2020 18:22:01

US3532063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:35:08
User entered empty.	Kathy Stephens (b) (4)	09 Nov 2020 18:22:01

US3532063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:35:08
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	09 Nov 2020 18:22:12

US3532063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:11:45
User entered 'I'	System	09 Nov 2020 18:22:12

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Dec 2020 18:57:52

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '15 Dec 2020'	Kathy Stephens (b) (4)	16 Dec 2020 18:57:52

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	16 Dec 2020 18:57:52

US3532063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	16 Dec 2020 18:57:52

US3532063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	16 Dec 2020 18:57:56

US3532063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User entered 'I'	System	16 Dec 2020 18:57:56

US3532063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	30 Jan 2021 22:40:46

US3532063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	30 Jan 2021 22:40:46

US3532063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	30 Jan 2021 22:40:46

US3532063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	30 Jan 2021 22:40:46

US3532063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	30 Jan 2021 22:40:49

US3532063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User entered '1'	System	30 Jan 2021 22:40:49

US3532063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:53

US3532063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:53

US3532063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 15:42:53

US3532063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	11 Feb 2021 15:42:53

US3532063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:58

US3532063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:07:52
User entered 'I'	System	11 Feb 2021 15:42:58

US3532063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:24:18
User closed query 'Per CDM: Please complete Vital signs form. If confirmed the visits Visit 4 Day 209(1) and OL-D57(1) occurred on the same day (11 MAR 2021), the data in these two visits must match. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 09:13:50
Query 'Per CDM: Please complete Vital signs form. If confirmed the visits Visit 4 Day 209(1) and OL-D57(1) occurred on the same day (11 MAR 2021), the data in these two visits must match. Please review and reconcile' answered with 'entered' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	03 Apr 2021 16:23:01
User opened query 'Per CDM: Please complete Vital signs form. If confirmed the visits Visit 4 Day 209(1) and OL-D57(1) occurred on the same day (11 MAR 2021), the data in these two visits must match. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:35:09
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	13 Mar 2021 17:27:36

US3532063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:24:18
User entered '11 Mar 2021'	(b) (4) Kathy Stephens (b) (4)	13 Mar 2021 17:27:36

US3532063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:24:18
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	13 Mar 2021 17:27:36

US3532063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'VISIT4'	System	13 Mar 2021 17:27:36

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Mar 2021'	Laila Hussaini (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:27'	(b) (4) Laila Hussaini (b) (4) (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered '11 Mar 2021 08:27'	System	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '97.0' F	Laila Hussaini (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Laila Hussaini (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	(b) (4) Laila Hussaini (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '79'	(b) (4) Laila Hussaini (b) (4) (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'bpm'	System	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '18'	(b) (4) Laila Hussaini (b) (4) (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'breaths/min'	System	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '112'	(b) (4) Laila Hussaini (b) (4) (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'mmHg'	System	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '72'	(b) (4) Laila Hussaini (b) (4) (b) (4)	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'mmHg'	System	01 Apr 2021 18:48:20

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38

US3532063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38

US3532063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'No (N)'	Kathy Stephens (b) (4)	13 Mar 2021 17:27:56

US3532063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	13 Mar 2021 17:27:56

US3532063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:28:11

US3532063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Mar 2021'	Kathy Stephens (b) (4)	13 Mar 2021 17:28:11

US3532063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:35'	Kathy Stephens (b) (4)	13 Mar 2021 17:28:11

US3532063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered '11 Mar 2021 08:35'	System	13 Mar 2021 17:28:11

US3532063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:28:15

US3532063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:03:38
User entered 'I'	System	13 Mar 2021 17:28:15

US3532063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:47:00
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	19 Apr 2021 12:11:55
	(b) (4)	

US3532063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:47:00
	(b) (4)	
User entered '17 Apr 2021'	Kathy Stephens (b) (4)	19 Apr 2021 12:11:55
	(b) (4)	

US3532063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:47:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	19 Apr 2021 12:11:55

US3532063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:47:00
User entered empty.	(b) (4)	
	Kathy Stephens (b) (4)	19 Apr 2021 12:11:55
	(b) (4)	

US3532063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	20 Apr 2021 15:47:00
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	19 Apr 2021 12:12:09

US3532063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 12:12:09

US3532063

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:24

US3532063

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:24

US3532063

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:24

US3532063

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 14:22:24

US3532063

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46

US3532063

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:37:00

US3532063

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:37:00

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Placebo (Placebo)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46

US3532063

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:36:44
User entered 'Placebo (Placebo)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:36:44
User entered 'Placebo (Placebo)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:22:46

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '1'	System	13 Jan 2021 14:22:46

US3532063

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'I'	System	13 Jan 2021 14:22:46

US3532063

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered empty.	System	13 Jan 2021 14:24:34
DataPoint set to visible.	System	13 Jan 2021 14:22:46

US3532063

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

US3532063

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered empty.	System	13 Jan 2021 14:24:34
DataPoint set to visible.	System	13 Jan 2021 14:22:46

US3532063

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User accepted default value 'Pre-Dose (PREDOSE)'	Kathy Stephens (b) (4) (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:46'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '13 Jan 2021 08:46'	System	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '97.0' F	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

US3532063

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '68'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'bpm'	System	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '16'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'breaths/min'	System	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '132'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '68'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

US3532063

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered missing code ND - Not Done.	Kathy Stephens (b) (4)	13 Jan 2021 14:24:34

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered empty.	System	13 Jan 2021 14:24:34
DataPoint set to visible.	System	13 Jan 2021 14:22:46

US3532063

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '10:01'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '13 Jan 2021 10:01'	System	13 Jan 2021 15:02:52

US3532063

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 15:04:53
User entered '97.1' F reason for change: Data Entry Error	Lisa Macoy (b) (4)	13 Jan 2021 15:04:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 15:02:52
User entered '97.1' (non-conformant).	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '64'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'bpm'	System	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '18'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'breaths/min'	System	13 Jan 2021 15:02:52

US3532063

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '121'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Jan 2021 15:02:52

US3532063

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '73'	Lisa Macoy (b) (4)	13 Jan 2021 15:02:52

US3532063

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Jan 2021 15:02:52

US3532063

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:45

US3532063

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:24:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mRNA-1273'	System	13 Jan 2021 14:49:45
DataPoint set to visible.	System	13 Jan 2021 14:22:46

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '09:30'	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '13 Jan 2021 09:30'	System	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Left Arm (LEFT ARM)'	Lisa Macoy (b) (4)	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'ONCE'	System	13 Jan 2021 14:49:45

US3532063

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 14:49:45

US3532063

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:02

US3532063

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:02

US3532063

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '09:05'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:02

US3532063

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '13 Jan 2021 09:05'	System	13 Jan 2021 14:23:02

US3532063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:14

US3532063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '13 Jan 2021'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:14

US3532063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:55'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:14

US3532063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '13 Jan 2021 08:55'	System	13 Jan 2021 14:23:14

US3532063

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

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Jan 2021 14:23:19

US3532063

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

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'I'	System	13 Jan 2021 14:23:19

US3532063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	21 Jan 2021 19:42:47

US3532063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '21 Jan 2021'	Kathy Stephens (b) (4)	21 Jan 2021 19:42:47

US3532063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	21 Jan 2021 19:42:47

US3532063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	21 Jan 2021 19:42:47

US3532063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	21 Jan 2021 19:42:59

US3532063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'I'	System	21 Jan 2021 19:42:59

US3532063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '1'	System	21 Jan 2021 19:42:59
DataPoint set to visible.	System	21 Jan 2021 19:42:59

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 14:21:22

US3532063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 14:21:22

US3532063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	11 Feb 2021 14:21:22

US3532063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'OLD29'	System	11 Feb 2021 14:21:22

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User accepted default value 'Pre-Dose (PREDOSE)'	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '08:03' reason for change: Data Entry Error	System	11 Feb 2021 15:40:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kathy Stephens (b) (4)	11 Feb 2021 15:40:57
User entered '03:' (non-conformant).	(b) (4)	
	System	11 Feb 2021 15:40:35
	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '11 Feb 2021 08:03'	System	11 Feb 2021 15:40:57
User entered '11 Feb 2021 03:.' (non-conformant).	System	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '97.3' F	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	11 Feb 2021 15:40:57
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Feb 2021 15:40:57
User entered '72' reason for change: Data Entry Error	Kathy Stephens (b) (4)	11 Feb 2021 15:40:57
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	11 Feb 2021 15:40:35
User entered '172'	System	11 Feb 2021 15:40:35
	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'bpm'	System	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '16'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'breaths/min'	System	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '107'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '64'	Kathy Stephens (b) (4)	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	11 Feb 2021 15:40:35

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User accepted default value 'Post-Dose (POSTDOSE)'	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '09:29'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '11 Feb 2021 09:29'	System	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '98.0' F	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '62'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'bpm'	System	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '16'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'breaths/min'	System	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '110'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '68'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	11 Feb 2021 15:41:46

US3532063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:58

US3532063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 15:41:58

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mRNA-1273'	System	11 Feb 2021 15:42:22
DataPoint set to visible.	System	21 Jan 2021 19:42:59

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Feb 2021'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:57'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '11 Feb 2021 08:57'	System	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Left Arm (LEFT ARM)'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'ONCE'	System	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 15:42:22

US3532063

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Feb 2021 15:42:33

US3532063

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'I'	System	11 Feb 2021 15:42:33

US3532063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:13

US3532063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '20 Feb 2021'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:13

US3532063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Contact Made (CONTACT MADE)'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:13

US3532063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	13 Mar 2021 17:25:13

US3532063

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:17

US3532063

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'I'	System	13 Mar 2021 17:25:17

US3532063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:33

US3532063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Mar 2021'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:33

US3532063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	13 Mar 2021 17:25:33

US3532063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'OLD57'	System	13 Mar 2021 17:25:33

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Mar 2021 17:26:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	13 Mar 2021 17:26:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Mar 2021 17:26:26
	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Mar 2021'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:27'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '11 Mar 2021 08:27'	System	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '97.0' F	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '79'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'bpm'	System	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '18'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'breaths/min'	System	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '112'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '72'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered 'mmHg'	System	13 Mar 2021 17:26:26

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42

US3532063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42

US3532063

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'No (N)'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:38

US3532063

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered empty.	Kathy Stephens (b) (4)	13 Mar 2021 17:26:38

US3532063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:52

US3532063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '11 Mar 2021'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:52

US3532063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
User entered '08:35'	Kathy Stephens (b) (4)	13 Mar 2021 17:26:52

US3532063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:12:42
User entered '11 Mar 2021 08:35'	System	13 Mar 2021 17:26:52

US3532063

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:08:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:28
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:10:51
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:32:04

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:32
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 17:43:27

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:59:16
User closed query 'please add "Left" to the term' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:59:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 21:18:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	09 Apr 2021 21:18:46
Query 'please add "Left" to the term' answered with 'done' (Site from CRA).	Kathy Stephens (b) (4)	09 Apr 2021 21:17:39
Data point term sent to Coder	System	09 Apr 2021 21:17:28
DataPoint Un-verified.	Kathy Stephens (b) (4)	09 Apr 2021 21:17:22
Coding entries removed.	(b) (4)	
	Kathy Stephens (b) (4)	09 Apr 2021 21:17:22
Signature has been broken.	(b) (4)	
	Kathy Stephens (b) (4)	09 Apr 2021 21:17:22
User entered 'FRACTURED left FEMUR' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 21:17:22
User opened query 'please add "Left" to the term' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:03:34
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 23:07:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	03 Nov 2020 23:07:26
Data point term sent to Coder	System	03 Nov 2020 22:42:36
User entered 'Fractured femur'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '28 Oct 2020'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 16:30:42
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 18:40:47
User closed query 'please verify end date as date of surgical repair was 29Oct2020' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:40:44
Query 'please verify end date as date of surgical repair was 29Oct2020' answered with 'noted in Comments' (Site from CRA).	Kathy Stephens (b) (4)	05 Mar 2021 18:31:47
	(b) (4)	
User opened query 'please verify end date as date of surgical repair was 29Oct2020' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:17:07
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 17:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:14:19
Query 'source = ongoing, please reconcile' canceled (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 18:22:40
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User opened query 'source = ongoing, please reconcile' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 18:20:54
User entered '27 Jan 2021' reason for change: Data Entry Error	Kathy Stephens (b) (4)	11 Feb 2021 16:30:42
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:33:50
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'No end date yet. ' (Site from Safety).	Kathy Stephens (b) (4)	18 Jan 2021 15:49:38
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:37:13
Query 'Re-issue PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:36:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Re-issue PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:36:40
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:42:00
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Healing. No new baseline yet' (Site from Safety).	Kathy Stephens (b) (4) (b) (4)	13 Nov 2020 22:38:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:25:13
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:00:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 17:43:03
User entered empty.	System	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:47:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:02:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:02:11
User entered 'I'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:11:08
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'collected 28OCT2020, Not detected Rapid NAAT.' (Site from Safety).	Kathy Stephens (b) (4)	20 Feb 2021 17:11:45
	(b) (4)	
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:03:13
User entered '28 Oct 2020'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:11:11
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'resent - previously provided on 17NOV2020' (Site from Safety).	Kathy Stephens (b) (4) (b) (4)	20 Feb 2021 17:07:02
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:02:56
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User closed query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:08:43
Query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'updated per subject' (Site from DM).	Kathy Stephens (b) (4)	12 Nov 2020 14:31:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Nov 2020 14:31:25
	(b) (4)	
User opened query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:19:04
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 05:18:33
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'obtaining records' (Site from System).	Kathy Stephens (b) (4)	03 Nov 2020 22:42:43
	(b) (4)	
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 22:42:22
User entered 'Unknown (UNK)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Related (NOT RELATED)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Related (NOT RELATED)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Applicable (NOT APPLICABLE)'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:21:29
User closed query 'Per DM CLR - RQ: Site's response noted. However, CM's indication are for Post Surgical issues and not this AE's direct verbatim. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:38:02
Query 'Per DM CLR - RQ: Site's response noted. However, CM's indication are for Post Surgical issues and not this AE's direct verbatim. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' answered with 'removed CM' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	18 Jan 2021 15:50:42
User entered '0' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	18 Jan 2021 15:50:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, CM's indication are for Post Surgical issues and not this AE's direct verbatim. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:31:51
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:47:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. (Site from DM).	Kathy Stephens (b) (4) (b) (4)	09 Jan 2021 19:53:08
' answered with 'meds 11-14 relate to the pain and post surgical issues' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4)	27 Nov 2020 14:18:18
	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'I'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	05 Mar 2021 17:14:27
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 18:22:00
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:16:38
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Status updated post Orthopedic assessment' (Site from Safety).	Kathy Stephens (b) (4)	11 Feb 2021 16:31:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	11 Feb 2021 16:30:42
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:25:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	03 Nov 2020 22:42:22
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
User closed query 'Per DM CLR: Narrative = SUBJECT FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 04:08:55
Query 'Per DM CLR: Narrative = SUBJECT FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'not separate' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	13 Mar 2021 17:29:21
User opened query 'Per DM CLR: Narrative = SUBJECT FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:11:58
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:40:57
DataPoint Un-verified.	Kathy Stephens (b) (4) (b) (4)	05 Mar 2021 18:31:33
User entered 'WHILE OUT OF TOWN, SUBJECT FELL AND FRACTURED L FEMUR. HOSPITALIZED AND SURGICALLY REPAIRED. HAS BEEN DISCHARGED FOR REHAB AND IS STILL OUT OF STATE. WILL OBTAIN HOSPITAL RECORDS RECORDS PROVIDED 11-17-20 Subject was followed by interim orthopedic group prior to returning home. End date was determined by home orthopedic assessment done upon return from out of state.' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	05 Mar 2021 18:31:33
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = SUBJECT FELL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:55:22
Query 'Per DM CLR: SAE Narrative = SUBJECT FELL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	Kathy Stephens (b) (4) (b) (4)	09 Jan 2021 19:50:23
' answered with 'Same AE' (Site from DM).		
User opened query 'Per DM CLR: SAE Narrative = SUBJECT FELL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	(b) (4), (b) (6)	12 Dec 2020 05:54:31
' (Site from DM).		
User entered 'WHILE OUT OF TOWN, SUBJECT FELL AND FRACTURED L FEMUR. HOSPITALIZED AND SURGICALLY REPAIRED. HAS BEEN DISCHARGED FOR REHAB AND IS STILL OUT OF STATE. WILL OBTAIN HOSPITAL RECORDS	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 23:41:18
RECORDS provided 11-17-20' reason for change: Data Entry Error		
User entered 'WHILE OUT OF TOWN, SUBJECT FELL AND FRACTURED L FEMUR. HOSPITALIZED AND SURGICALLY REPAIRED. HAS BEEN DISCHARGED FOR REHAB AND IS STILL OUT OF STATE. WILL OBTAIN HOSPITAL RECORDS	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 22:54:37
Records being sent.' reason for change: Data Entry Error		
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:42:15
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:42:12

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no hospital records available yet' (Site from Safety).	Kathy Stephens (b) (4) (b) (4)	13 Nov 2020 23:08:18
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'Accidental - Wet pavement and her dog on a leash.' (Site from Safety).	Kathy Stephens (b) (4) (b) (4)	13 Nov 2020 23:07:56
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	13 Nov 2020 13:25:31
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6) (b) (4)	13 Nov 2020 13:25:24
User entered 'While out of town, subject fell and fractured L femur. Hospitalized and surgically repaired. Has been discharged for rehab and is still out of state. Will obtain hospital records'	Kathy Stephens (b) (4) (b) (4)	03 Nov 2020 22:42:22

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 22:42:22

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 22:42:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 22:42:22

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53

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Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: 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)	19 Jan 2021 17:51:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 17:51:08
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST SURGICAL PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 05:33:32
Data point term sent to Coder	System	18 Jan 2021 15:49:15
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST SURGICAL PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'done' (Site from DM).	Kathy Stephens (b) (4)	18 Jan 2021 15:48:48
Coding entries removed.	Kathy Stephens (b) (4)	18 Jan 2021 15:48:35
User entered 'POST SURGICAL PAIN (Repair of Fractured femur)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	18 Jan 2021 15:48:35
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST SURGICAL PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:32:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: 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)	10 Dec 2020 17:02:57

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Dec 2020 17:02:57
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Dec 2020 17:02:18
User entered 'Post surgical pain'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '29 Oct 2020'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User entered empty.	System	10 Dec 2020 17:01:37

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Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '11 Nov 2020'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User entered empty.	System	10 Dec 2020 17:01:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	16 Dec 2020 18:46:54
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	16 Dec 2020 18:46:35
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	16 Dec 2020 18:46:54
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	16 Dec 2020 18:46:54
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	16 Dec 2020 18:46:35
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Related (NOT RELATED)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Related (NOT RELATED)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Not Applicable (NOT APPLICABLE)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'I'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered '0'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:07:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:21:29
User entered empty.	Kathy Stephens (b) (4)	10 Dec 2020 17:01:37
	(b) (4)	

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User entered '0'	System	10 Dec 2020 17:01:37

US3532063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53
User entered '1'	System	10 Dec 2020 17:01:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:09:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:08:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	18 Aug 2020 19:00:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 09:16:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 09:16:39
Data point term sent to Coder	System	26 Aug 2020 17:37:05
User entered 'Omega 3'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '1200'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'mg (mg)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'once daily (QD)'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	13 Jan 2021 14:25:57
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:25:57
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User entered '1'	System	26 Aug 2020 17:36:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User entered '1'	System	26 Aug 2020 17:36:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:44:55
User entered '804 (804)'	System	26 Aug 2020 17:36:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 17:53:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:53:05
Data point term sent to Coder	System	26 Aug 2020 17:38:09
Data point term sent to Coder	System	26 Aug 2020 17:37:07
User entered 'calcium'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:36:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'health' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered '1000' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'mg (mg)' reason for change: New Information	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:38:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'once daily (QD)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:39:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:39:28
	(b) (4)	
User entered '0'	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:37:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:37:29
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	26 Aug 2020 17:37:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:36:50
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:36:50
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Aug 2020 17:38:39
User entered '1'	System	26 Aug 2020 17:37:29
User entered empty.	System	26 Aug 2020 17:36:50

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:37:29
User entered empty.	System	26 Aug 2020 17:36:50

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 17:37:29
User entered empty.	System	26 Aug 2020 17:36:50

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Aug 2020 11:45:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:45:39
Data point term sent to Coder	System	26 Aug 2020 17:39:11
User entered 'tumeric'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '1000'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'mg (mg)'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'twice daily (BID)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:38:23
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	26 Aug 2020 17:38:12
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	26 Aug 2020 17:38:23
User entered '0'	(b) (4)	
	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:26:35
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:26:35
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User entered '2'	System	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User entered '1'	System	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:26
User entered '804 (804)'	System	26 Aug 2020 17:38:12

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 17:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:53:49
Data point term sent to Coder	System	26 Aug 2020 17:41:21
User entered 'Multi vitamin'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'tablet (TABLET)'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'once daily (QD)'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	13 Jan 2021 14:32:24
User entered 'Yes (Y)'	(b) (4)	
	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:32:24
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User entered '1'	System	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User entered '1'	System	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:34
User entered '804 (804)'	System	26 Aug 2020 17:40:37

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Oct 2020 12:15:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:15:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: SUPER B COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 12:10:42
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 Aug 2020 12:10:42
Data point term sent to Coder	System	26 Aug 2020 17:42:24
User entered 'Super B vitamin'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:41:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	26 Aug 2020 17:43:15
	(b) (4)	
User entered '5000'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'tablet (TABLET)' reason for change:	Kathy Stephens (b) (4)	26 Aug 2020 17:43:15
Data Entry Error	(b) (4)	
User entered 'IU (IU)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'once daily (QD)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:41:54
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:41:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:41:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 17:41:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
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)	27 Aug 2020 17:54:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:54:02
Data point term sent to Coder	System	26 Aug 2020 17:43:26
User entered 'Vitamin D3'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:42:51

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered '5000'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'IU (IU)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'once daily (QD)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:42:51
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:42:51

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 17:42:51

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 17:42:51

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:54:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:54:08
Data point term sent to Coder	System	26 Aug 2020 17:44:27
User entered 'Vitamin E'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '400'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'IU (IU)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'once daily (QD)'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'I'	(b) (4) Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:33:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:33:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User entered '1'	System	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User entered '1'	System	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:16
User entered '804 (804)'	System	26 Aug 2020 17:44:05

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 14:56:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 14:56:44
Data point term sent to Coder	System	26 Aug 2020 17:45:30
User entered 'Glucosamine Chondroitin'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'health'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:01:01
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	27 Feb 2021 22:30:59
User entered '500/400' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	27 Feb 2021 22:30:52
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:17:59
User entered '500'	Kathy Stephens (b) (4) (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'mg (mg)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'twice daily (BID)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'I'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Jan 2021 18:56:07
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02
	(b) (4)	

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '30 Nov 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Jan 2021 18:56:07
User entered empty.	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User entered '2'	System	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User entered '1'	System	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:49
User entered '804 (804)'	System	26 Aug 2020 17:45:02

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
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)	11 Oct 2020 05:09:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:09:16
Data point term sent to Coder	System	10 Oct 2020 22:44:59
User entered 'flu ad'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'annual flu vaccine'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '0.5'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'mg (mg)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'once (ONCE)'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered empty.	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '7 Oct 2020'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '0'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered '7 Oct 2020'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User entered 'No (N)'	Kathy Stephens (b) (4)	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User entered empty.	System	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User entered empty.	System	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:56
User entered empty.	System	10 Oct 2020 22:44:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:42:55
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 Nov 2020 01:42:55
Data point term sent to Coder	System	17 Nov 2020 01:42:28
User entered 'eliquis'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:41
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:42
User entered 'Post surgical DVT prophylaxis'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:46
User entered '2.5'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:47
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:49
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:50
User entered 'twice daily (BID)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:53
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:57
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:55
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:27:58
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:19
User entered '0'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:21
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Jan 2021 18:55:33
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:24
User entered '16 Dec 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Jan 2021 18:55:33
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:34
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User entered '2'	System	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User entered '1'	System	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:06
User entered '804 (804)'	System	17 Nov 2020 01:42:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:26:51
Data point term sent to Coder	System	24 Jan 2021 16:07:58
Coding entries removed.	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:07:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:22:50
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 Nov 2020 02:22:50
Data point term sent to Coder	System	17 Nov 2020 01:43:28
User entered 'flexeril'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	10 Dec 2020 16:51:12
User entered 'No (N)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:48
User closed query 'Per DM CLR: Please provide the specific location of post surgical muscle spasms (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 04:50:41
Query 'Per DM CLR: Please provide the specific location of post surgical muscle spasms (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'done' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:08:00
User entered 'POST SURGICAL MUSCLE leg SPASMS following repair of fractured femur' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:07:51
User opened query 'Per DM CLR: Please provide the specific location of post surgical muscle spasms (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 03:22:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 13:30:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'used prophylactically if needed' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	10 Dec 2020 16:51:53

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:15:49
User entered 'post surgical muscle spasms'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:52
User entered '5'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:54
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:28:56
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:50:59
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:06
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:08
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:10
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:11
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:13
User entered '0'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:16
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Jan 2021 18:55:10
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:18
User entered '16 Dec 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Jan 2021 18:55:10
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:20
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User entered empty.	System	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User entered empty.	System	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:14
User entered empty.	System	17 Nov 2020 01:43:11

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:27
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)	17 Nov 2020 02:12:50
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 Nov 2020 02:12:50
Data point term sent to Coder	System	17 Nov 2020 01:44:28
User entered 'Colace'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:29
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:31
User entered 'Post surgical constipation'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:34
User entered '100'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:36
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:37
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:39
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:42
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:43
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:45
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:47
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:49
User entered '0'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:51
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Jan 2021 18:54:45
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:53
User entered '16 Dec 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Jan 2021 18:54:45
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:51:54
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User entered empty.	System	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User entered empty.	System	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:22
User entered empty.	System	17 Nov 2020 01:43:57

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:25:51
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 Nov 2020 03:25:51
Data point term sent to Coder	System	17 Nov 2020 01:45:29
User entered 'Zofran'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:15
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 13:31:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'prevention only' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	10 Dec 2020 16:54:57
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:16:32
User entered 'post surgical nausea'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:23
User entered '4'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:24
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:26
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:28
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:29
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:32
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:34
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:35
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:37
User entered '0'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:40
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	10 Dec 2020 16:56:07
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:44
User entered '11 Nov 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	10 Dec 2020 16:56:07
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:46
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User entered empty.	System	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User entered empty.	System	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:29
User entered empty.	System	17 Nov 2020 01:45:01

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 21:04:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 21:04:58
Data point term sent to Coder	System	24 Jan 2021 16:07:57
Coding entries removed.	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:07:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:04:53
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 Nov 2020 07:04:53
Data point term sent to Coder	System	17 Nov 2020 01:46:29
User entered 'Percoset'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:55
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:00
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 04:50:56
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'done' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:07:21
User entered 'POSTSURGICAL Leg PAIN - following repair of fractured femur' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	24 Jan 2021 16:07:13
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 03:22:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 04:46:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'added to MH' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	10 Dec 2020 17:06:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:16:11
User entered 'Postsurgical pain'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:02
User entered '7.5/325'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:04
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:08
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:09
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:10
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:12
User entered 'Oral (ORAL)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:13
User entered empty.	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:16
User entered '01 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:17
User entered '0'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:19
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	17 Jan 2021 18:53:55
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:20
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Jan 2021 18:53:55
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Jan 2021 18:53:48
User entered '11 Nov 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	17 Jan 2021 18:53:48
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:22
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User entered empty.	System	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User entered empty.	System	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:54
User entered empty.	System	17 Nov 2020 01:45:54

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:32:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:32:46
Data point term sent to Coder	System	03 Mar 2021 21:35:37
User entered 'Propofol injection'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:31
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:32
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:36
User entered '100'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:37
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:39
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:40
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:43
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:45
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:47
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:49
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:52
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:53
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:56
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:53:58
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User entered empty.	System	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User entered empty.	System	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:13
User entered empty.	System	03 Mar 2021 21:35:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:38:04
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 Mar 2021 07:38:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:54:10
Data point term sent to Coder	System	03 Mar 2021 21:38:39
User entered 'midazolam'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:12
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:16
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:17
User entered '2'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:19
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:21
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:23
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:24
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:26
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:30
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:31
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:33
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:35
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 21:37:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 21:37:59
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 21:37:40
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:37
User entered '29 Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	03 Mar 2021 21:37:59
User entered empty.	(b) (4) Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:39
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 21:37:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 21:37:59
User entered 'No (N)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 21:37:40
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User entered empty.	System	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User entered empty.	System	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:38
User entered empty.	System	03 Mar 2021 21:37:40

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:10:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:10:46
Data point term sent to Coder	System	03 Mar 2021 21:40:41
User entered 'Lidocaine (PF) 1% injection'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:53
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:55
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:54:58
User entered '5'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:00
User entered 'mL (mL)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:02
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:03
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:05
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:06
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:09
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:11
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:12
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:14
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:18
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:55:22
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User entered empty.	System	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User entered empty.	System	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:16
User entered empty.	System	03 Mar 2021 21:40:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:40:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:40:40
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:56:49
Data point term sent to Coder	System	03 Mar 2021 21:43:45
User entered 'rocuronium injection'	Kathy Stephens (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:56:51
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:56:53
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:56:58
User entered '50'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:56:59
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:01
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:02
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:04
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:07
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:09
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:11
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:14
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:15
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:17
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:20
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User entered empty.	System	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User entered empty.	System	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:50
User entered empty.	System	03 Mar 2021 21:43:22

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:12:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:12:03
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:57:41
Data point term sent to Coder	System	03 Mar 2021 21:44:46
User entered 'fentanyl injection'	Kathy Stephens (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:44
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:47
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:51
User entered '50'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:53
User entered 'ug (ug)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:54
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:56
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:57:57
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:00
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:01
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:04
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:06
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:08
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:09
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:12
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User entered empty.	System	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User entered empty.	System	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:53
User entered empty.	System	03 Mar 2021 21:44:29

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:29:43
Data point term sent to Coder	System	05 Mar 2021 18:23:06
Coding entries removed.	Kathy Stephens (b) (4)	05 Mar 2021 18:23:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:58:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 22:15:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 22:15:40
Data point term sent to Coder	System	03 Mar 2021 21:45:47
User entered 'decadron'	Kathy Stephens (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:25
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:26
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:29
User entered '8'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:30
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:32
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:35
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:58:37
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:40:23
User closed query 'source = IV, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:40:21
Query 'source = IV, please verify' answered with 'updated' (Site from CRA).	Kathy Stephens (b) (4) (b) (4)	05 Mar 2021 18:23:10
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	05 Mar 2021 18:23:02
User opened query 'source = IV, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:59:09
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:58:43
User entered 'Rectal (RECTAL)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:12
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:14
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:15
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:18
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:20
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:21
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User entered empty.	System	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User entered empty.	System	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:09
User entered empty.	System	03 Mar 2021 21:45:31

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 11:21:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 11:21:50
Data point term sent to Coder	System	03 Mar 2021 21:46:50
User entered 'zofran'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:44
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:46
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:49
User entered '4'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:51
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:53
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:55
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:58
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:02
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:05
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:07
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:09
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:11
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:13
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:15
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User entered empty.	System	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User entered empty.	System	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:48:57
User entered empty.	System	03 Mar 2021 21:46:35

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:25
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX SODIUM, PRODUCTSYNONYM: BRIDION - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 21:48:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 21:48:44
Data point term sent to Coder	System	03 Mar 2021 21:47:50
User entered 'bridion'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:32
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:34
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:38
User entered '300'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:44
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:46
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:51
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:55
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:57
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:00:59
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:01
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:04
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:05
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:07
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:10
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User entered empty.	System	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User entered empty.	System	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:29
User entered empty.	System	03 Mar 2021 21:47:25

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:16
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: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEFADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:33:09
Data point term sent to Coder	System	03 Mar 2021 21:48:51
User entered 'Ancef'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:24
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:26
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:29
User entered '2'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:31
User entered 'g (g)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:33
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:34
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:36
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:37
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:41
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:42
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:44
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:46
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:50
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:01:51
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User entered empty.	System	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User entered empty.	System	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:51:02
User entered empty.	System	03 Mar 2021 21:48:30

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 07:31:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:31:53
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:01:59
Data point term sent to Coder	System	03 Mar 2021 21:50:55
User entered 'ephedrine'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:04
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:06
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:09
User entered '20'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:11
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:13
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:16
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:18
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:20
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:22
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:25
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:27
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:29
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:30
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:33
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User entered empty.	System	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User entered empty.	System	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:31
User entered empty.	System	03 Mar 2021 21:50:45

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 12:47:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:47:50
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:02:39
Data point term sent to Coder	System	03 Mar 2021 21:54:58
User entered 'morphine'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:02:56
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:00
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:03
User entered '2'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:05
User entered 'mg (mg)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:07
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:08
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:11
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:13
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:16
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:20
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:22
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:25
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:26
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:28
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User entered empty.	System	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User entered empty.	System	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:59
User entered empty.	System	03 Mar 2021 21:54:23

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
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: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:37:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:37:01
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:03:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 00:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 00:20:46
Data point term sent to Coder	System	03 Mar 2021 21:56:04
User entered '0.9% sodium chloride infusion'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:36
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:38
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:41
User entered '10-125'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:42
User entered 'mL (mL)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:44
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:46
User entered 'as needed (PRN)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:47
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:50
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:51
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:53
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:55
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:03:58
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:00
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:03
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User entered empty.	System	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User entered empty.	System	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:55:50
User entered empty.	System	03 Mar 2021 21:55:47

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
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)	17 Mar 2021 11:08:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:08:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:04:08
Data point term sent to Coder	System	03 Mar 2021 21:57:06
User entered 'Lactated Ringers infusion'	Kathy Stephens (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:10
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:12
User entered 'Concomitant procedure # 1. Surgical repair of L femoral fracture'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:17
User entered '1000'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:19
User entered 'mL (mL)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:04:20
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:09:59
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:00
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:04
User entered 'Intravenous (INTRAVENOUS)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:07
User entered empty.	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:08
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:11
User entered '0'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:13
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:15
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:17
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User entered empty.	System	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User entered empty.	System	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:47:10
User entered empty.	System	03 Mar 2021 21:56:48

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:08:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:09:57
User entered 'Yes (Y)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 18:50:43

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered '29 Oct 2020'	Kathy Stephens (b) (4)	11 Nov 2020 18:51:37
	(b) (4)	

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:39:47
	(b) (4), (b) (6)	
User closed query 'source = Surgical Repair of L Femoral Fracture, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:39:46
Query 'source = Surgical Repair of L Femoral Fracture, please verify' answered with 'updated' (Site from CRA).	Kathy Stephens (b) (4)	05 Mar 2021 18:24:31
	(b) (4)	
User entered 'SURGICAL REPAIR OF Left FRACTURED FEMUR' reason for change: Data Entry Error	Kathy Stephens (b) (4)	05 Mar 2021 18:24:25
	(b) (4)	
User opened query 'source = Surgical Repair of L Femoral Fracture, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:12:10
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 18:11:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:10:54
	(b) (4), (b) (6)	
User entered 'Surgical repair of fractured femur'	Kathy Stephens (b) (4)	11 Nov 2020 18:51:37
	(b) (4)	

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered 'Adverse Event (AE)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 18:51:37

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:04

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered empty.	Kathy Stephens (b) (4)	11 Nov 2020 18:51:37
	(b) (4)	

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:08:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:48:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered '1 Dec 2020'	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 16:34:21

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:08:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:48:22
User closed query 'please add XRay Hip and Pelvis done 28Oct20and 29Oct20 for AE 01' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:18:36
Query 'please add XRay Hip and Pelvis done 28Oct20and 29Oct20 for AE 01' answered with 'added' (Site from CRA).	Kathy Stephens (b) (4) (b) (4)	09 Apr 2021 16:18:46
User opened query 'please add XRay Hip and Pelvis done 28Oct20and 29Oct20 for AE 01' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:54:38
Query 'please add XRay Hip and Pelvis done 28Oct20 for AE 01' canceled (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:54:30
User opened query 'please add XRay Hip and Pelvis done 28Oct20 for AE 01' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:44:24
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered 'Physical Therapy'	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 16:34:21

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:48:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered 'Adverse Event (AE)'	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 16:34:21

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:08:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:48:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:54
User entered empty.	Kathy Stephens (b) (4) (b) (4)	11 Feb 2021 16:34:21

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:08:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:49:57
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
User closed query 'please add XRay Hip and Pelvis done 29Oct20 for AE 01' (Site from CRA).	(b) (4)	
Query 'please add XRay Hip and Pelvis done 29Oct20 for AE 01' answered with 'added 29OCT2020' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:57:20
User opened query 'please add XRay Hip and Pelvis done 29Oct20 for AE 01' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:04:47
DataPoint Verified.	(b) (4)	
User entered '28 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 17:19:06
	(b) (4), (b) (6)	12 Apr 2021 17:18:43
	(b) (4)	
	Kathy Stephens (b) (4)	09 Apr 2021 16:18:29
	(b) (4)	

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:08:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:49:57
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:18:47
User entered 'Xray of hips and pelvis'	Kathy Stephens (b) (4) (b) (4)	09 Apr 2021 16:18:29

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:49:57
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:18:45
User entered 'Adverse Event (AE)'	Kathy Stephens (b) (4) (b) (4)	09 Apr 2021 16:18:29

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:08:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:49:57
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:18:48
User entered empty.	Kathy Stephens (b) (4) (b) (4)	09 Apr 2021 16:18:29

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:08:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:50:00
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:57:27
User entered '29 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 19:51:50

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:08:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:50:00
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:57:27
User entered 'Xray of hip and pelvis'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 19:51:50

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:08:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:50:00
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:57:27
User entered 'Adverse Event (AE)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 19:51:50

US3532063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:08:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:50:00
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:57:27
User entered empty.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 19:51:50

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '04/Nov/2020 12:44'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
	(b) (4), (b) (6)	
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '17/Nov/2020 09:43'	System	17 Nov 2020 14:43:50

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:46:18
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 14:43:50

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
	(b) (4), (b) (6)	
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '18/Nov/2020 08:46'	System	18 Nov 2020 13:46:43

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:37:03
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 13:46:43

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
	(b) (4), (b) (6)	
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '19/Jan/2021 12:10'	System	19 Jan 2021 17:10:53

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:11:20
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 17:10:53

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '12/Feb/2021 11:16'	System	12 Feb 2021 16:16:57

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:17:04
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 16:16:57

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
	(b) (4), (b) (6)	
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered '22/Feb/2021 11:11'	System	22 Feb 2021 16:11:53

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 16:04:37
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 16:11:53

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:05:17
User entered '08/Mar/2021 11:04'	System	08 Mar 2021 16:04:51

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:08:04

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)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:56:18
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:05:17
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 16:04:51

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered	System	04 Nov 2020 17:43:27
'USA-US077-2020-MRNA-1273-P301000007'		

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Yes (Y)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'No (N)'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Evan'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'Anderson'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '2015 Uppergate Drive'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered 'GA'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:43:53
User entered '30323'	System	04 Nov 2020 17:43:27

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:58:27
DataPoint Verified.	(b) (4)	02 Mar 2021 18:27:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:43:41
	(b) (4), (b) (6)	
User entered 'US'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 18:56:31
User entered '7'	System	08 Mar 2021 16:04:51
User entered '6'	System	22 Feb 2021 16:11:53
User entered '5'	System	12 Feb 2021 16:16:57
User entered '4'	System	19 Jan 2021 17:10:53
User entered '3'	System	18 Nov 2020 13:46:43
User entered '2'	System	17 Nov 2020 14:43:50
User entered '1'	System	04 Nov 2020 17:44:05

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:08:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
User entered '12/Apr/2021 14:56'	(b) (4) System	12 Apr 2021 18:56:31

US3532063

Folder: SAE USA-US077-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:08:04

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.	Evan Anderson (b) (4)	16 Apr 2021 08:36:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:56:31