

US3432240 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:36:40

All time stamps listed in this document are displayed in GMT

US3432240

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 02:08:08

Generated On: 09 Jun 2021 17:36:40

Participant ID

US3432240

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

US3432240

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3432240

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" 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

US3432240

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Date of Informed Consent (*dd MMM yyyy*) 21 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

US3432240

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3432240

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432240

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432240

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3432240

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3432240

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	BASAL CELL CANCER SKIN
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	DYSPLASTIC NEVI
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)	

US3432240

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	C-SPINE STENOSIS
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3432240

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Condition	L SHOULDER ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432240

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:22 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:22
Height (<i>xxx.x</i>)	174.7 cm
Weight (<i>xxx.x</i>)	107.5 kg
BMI (<i>xxx.x</i>)	35.22270 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3432240

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:10

Generated On: 09 Jun 2021 17:36:40

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) 19 Feb 2021 02:08:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	22 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3432240

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 187776

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) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Height	176 cm
Weight	106.7 kg

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Height	176 cm
Weight	106.7 kg
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)	22 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 10:44
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	065 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	086 mmHg
Diastolic Blood Pressure units	MMHG

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Height	176 cm
Weight	106.7 kg
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 11:54
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG

US3432240

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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) 22 AUG 2020

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

Treatment Date and Time (derived) 22 AUG 2020 11:23

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

US3432240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 AUG 2020

Collection time (00:00-23:59)

11:02 (24 HR)

Collection date and time (derived)

22 AUG 2020 11:02

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	22 AUG 2020 11:10
Nasopharyngeal Swab 2	No		

US3432240

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 AUG 2020 11:57

PC Open Date & Time 22 AUG 2020 11:43

PC Close Date & Time 22 AUG 2020 14:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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 97.4 °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	22 AUG 2020 21:00
PC Open Date & Time	22 AUG 2020 15:08
PC Close Date & Time	23 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

97.7 °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 18:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 22:47

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

96.8 °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

26 AUG 2020 18:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

95.2 °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

27 AUG 2020 20:15

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

96.2 °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

28 AUG 2020 14:32

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 11:59

PC Open Date & Time

22 AUG 2020 11:43

PC Close Date & Time

22 AUG 2020 14:13

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

22 AUG 2020 21:02

PC Open Date & Time

22 AUG 2020 15:08

PC Close Date & Time

23 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

23 AUG 2020 18:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

24 AUG 2020 19:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

25 AUG 2020 22:47

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

26 AUG 2020 18:10

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

27 AUG 2020 20:16

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

28 AUG 2020 14:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 11:59
PC Open Date & Time	22 AUG 2020 11:43
PC Close Date & Time	22 AUG 2020 14:13

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 21:02
PC Open Date & Time	22 AUG 2020 15:08
PC Close Date & Time	23 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:09
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 22:48
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:10
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

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)

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:16
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 14:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3432240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	25 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:41
Temperature (xxx.x)	036.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:44
Temperature (xxx.x)	036.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	054 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	020 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3432240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 11:13

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

US3432240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	10:58 (24 HR)
Collection date and time (derived)	25 SEP 2020 10:58

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:02	25 SEP 2020 11:02
Nasopharyngeal Swab 2	No		

US3432240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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):

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

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

PC Time Stamp 25 SEP 2020 11:50

PC Open Date & Time 25 SEP 2020 11:33

PC Close Date & Time 25 SEP 2020 14:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 25 SEP 2020 14:58

PC Close Date & Time 26 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °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):

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

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

PC Time Stamp 26 SEP 2020 18:14

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

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 96.9 °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):

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

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

PC Time Stamp 27 SEP 2020 20:52

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 SEP 2020 16:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 21:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 22:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

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.

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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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 OCT 2020 05:48

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 11:51

PC Open Date & Time

25 SEP 2020 11:33

PC Close Date & Time

25 SEP 2020 14:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

25 SEP 2020 14:58

PC Close Date & Time

26 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

55

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

26 SEP 2020 18:15

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

27 SEP 2020 20:53

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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)

5

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

28 SEP 2020 16:26

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

29 SEP 2020 21:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

30 SEP 2020 22:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

02 OCT 2020 05:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 11:51
PC Open Date & Time	25 SEP 2020 11:33
PC Close Date & Time	25 SEP 2020 14:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 14:58

PC Close Date & Time

26 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

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)

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:54
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

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 ☒

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:26
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

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EAB) (1725)

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 21:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

EAB) (1725)

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US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 22:41
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 05:49
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3432240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	28 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:38
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

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.

US3432240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

12:46 (24 HR)

Collection date and time (derived)

28 OCT 2020 12:46

US3432240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:26

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

22 OCT 2020 04:52:01

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

29 OCT 2020 04:46:23

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 17:59:25

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 14:44:39

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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	23 NOV 2020 04:58:08
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

02 DEC 2020 12:00:31

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

07 DEC 2020 04:38:17

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

14 DEC 2020 03:16:59

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 05:07:14
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

28 DEC 2020 14:34:23

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

05 JAN 2021 11:09:50

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

11 JAN 2021 14:38:12

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

18 JAN 2021 16:41:29

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

25 JAN 2021 03:48:45

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

04 FEB 2021 15:07:38

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

08 FEB 2021 02:57:12

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 00:02:40
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

22 FEB 2021 03:55:23

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

03 MAR 2021 12:00:33

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 04:41:54

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 <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	15 MAR 2021 00:06:34
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

22 MAR 2021 00:02:33

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

29 MAR 2021 05:54:12

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

07 APR 2021 12:32:11

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

12 APR 2021 05:14:03

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

19 APR 2021 05:18:37

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

28 APR 2021 12:00:29

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

03 MAY 2021 00:24:31

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	18 JUN 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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°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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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°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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2022 00:01
Patient Cloud Close Date & Time	20 MAY 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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="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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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"/>

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	28 OCT 2022 23:59
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US3432240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:36:40

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		03 MAR 2021 12:01:31

US3432240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	31 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
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US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 MAR 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 10:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

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.

US3432240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 31 MAR 2021

Collection time (00:00-23:59) 10:20 (24 HR)

Collection date and time (derived) 31 MAR 2021 10:20

US3432240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 04:35:20

Generated On: 09 Jun 2021 17:36:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432240

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 04:35:20

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432240

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432240

Folder: Covid-19 Assessment 29 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:36:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432240

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

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

Visit date (dd MMM yyyy)	6 JAN 2021
--------------------------	------------

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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US3432240

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Date of updated informed consent (dd MMM yyyy) 6 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 6 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3432240

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	6 JAN 2021 10:40

US3432240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

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

Collection date (dd MMM yyyy)	6 JAN 2021
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Collection time (00:00 - 23:59)	10:44
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Collection Date and Time (derived)	6 JAN 2021 10:44
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US3432240

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 02:08:08

Generated On: 09 Jun 2021 17:36:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

AEID

Adverse event

FACIAL FLUSHING

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)

22 AUG 2020

Start time (00:00-23:59)

14:00 (24 HR)

AE start date and time (derived)

22 AUG 2020 14:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 AUG 2020

End time (00:00-23:59)

23:00 (24 HR)

AE End Date and Time (derived)

22 AUG 2020 23:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

AEID USA-US078-2021-MRNA-1273-P30
1000018

Adverse event L SHOULDER SEPTIC
ARTHRITIS

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) 08 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 19 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☒
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 08 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 12 MAR 2021

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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	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	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

ADMITTED 8MAR2021 FOR
ELECTIVE ROTATOR CUFF
REPAIR. FOUND TO HAVE
PURULENCE FROM PROXIMAL
HUMERUS AND GH JOINT.
HARDWARE REMOVED.
STARTED TREATMENT WITH
ANTIBIOTICS. NO SIGNS OR
SYMPTOMS OF INFECTION.

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

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 20:43:00

Generated On: 09 Jun 2021 17:36:40

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

Yes ☒

No ☐

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

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication LIPITOR

Prophylaxis Yes ☒
No ☐

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL 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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication CIALIS

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication DENTAL PROCEDURE

Dose per administration 875

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) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 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 (6)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication DENTAL PROCEDURE

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 (6)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication DENTAL IMPLANT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 OCT 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 (8)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

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 (8)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication L SHOULDER SEPTIC
ARTHRITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 APR 2021
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 (10)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication L SHOULDER SEPTIC
ARTHRITIS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication L SHOULDER SEPTIC
ARTHRITIS

Dose per administration 1500

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) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 (12)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication L SHOULDER ROTATOR CUFF
REPAIR

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

	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)		20 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (13)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication L SHOULDER ROTATOR CUFF
REPAIR

Dose per administration 2-4

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

6X DAILY PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 11:09:05

Generated On: 09 Jun 2021 17:36:40

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

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 02:08:09

Generated On: 09 Jun 2021 17:36:40

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) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 AUG 2020	BASAL CELL CARCINOMA REMOVAL SURGERY	Medical History	
12 SEP 2020	ELECTROMYOGRAPHY	Diagnostic	
23 SEP 2020	DENTAL IMPLANTS	Other	RECONSTRUCTIVE
08 MAR 2021	REMOVAL OF HARDWARE IN L SHOULDER	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:40

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:40

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 ☐

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/MAR/2021 11:31
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

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/APR/2021 10:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/APR/2021 06:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/APR/2021 09:51
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

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Apr 2021 11:09:06

Generated On: 09 Jun 2021 17:36:40

SAEID	USA-US078-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/APR/2021 09:31
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

US3432240 (Prod: Brigham and Womens Hospital)

US3432240

Form: Participant Creation

Generated On: 09 Jun 2021 17:36:40

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 02:46:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'US3432240'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:09:15

US3432240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:23
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:33

US3432240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:23
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:09:16

US3432240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:23
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:33

US3432240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'SCRN'	System	21 Aug 2020 22:57:33

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:09:17

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '69'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'YEARS'	System	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '69'	System	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered 'Male (M)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered 'l'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:40

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:48:41
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:57:53

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered '21 Aug 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Aug 2020'	System	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2020'	System	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered 'Amendment 2 (2)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:18

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:09:16

US3432240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'I'	System	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:23
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:36:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:50:01
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:58:37

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:19
Data point term sent to Coder	System	21 Aug 2020 23:00:04
User entered 'high cholesterol'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:01

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:18
Data point term sent to Coder	System	21 Aug 2020 23:00:04
User entered 'GERD'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 1990'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 1990'	System	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '1990'	System	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:17

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:00:18
Data point term sent to Coder	System	21 Aug 2020 23:00:04
User entered 'erectile dysfunction'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 22:59:35

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:02:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:02:19
Data point term sent to Coder	System	21 Aug 2020 23:01:05
User entered 'prostatectomy'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 23:00:22

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:02:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:02:21
Data point term sent to Coder	System	21 Aug 2020 23:02:06
User entered 'prostate cancer'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2005'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2005'	System	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2005'	System	21 Aug 2020 23:01:28

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 13:29:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 13:29:41
Data point term sent to Coder	System	21 Aug 2020 23:03:08
User entered 'basal cell cancer skin'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un Aug 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Aug 2020'	System	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2020'	System	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:02:41

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Dysplastic naevus, LLT: Dysplastic nevus - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:06:23
Data point term sent to Coder	System	21 Aug 2020 23:05:10
User entered 'dysplastic nevi'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un UNK 2000'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Jan 2000'	System	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2000'	System	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:05:00

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Shoulder fracture - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 03:53:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 03:53:25
Data point term sent to Coder	System	21 Aug 2020 23:06:13
User entered 'left shoulder fracture'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:23
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
Signature has been broken.	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
User entered 'UN Apr 2019' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un Apr 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:23
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
Signature has been broken.	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
User entered 'UN Apr 2019' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:38:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un Apr 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Apr 2019'	System	21 Apr 2021 16:38:26
User entered 'Apr 2020'	System	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2019'	System	21 Apr 2021 16:38:26
User entered '2020'	System	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Apr 2019'	System	21 Apr 2021 16:38:26
User entered 'Apr 2020'	System	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2019'	System	21 Apr 2021 16:38:26
User entered '2020'	System	21 Aug 2020 23:05:40

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Cervical spinal stenosis, LLT: Cervical spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 06:31:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 06:31:13
Data point term sent to Coder	System	21 Aug 2020 23:07:14
User entered 'c-spine stenosis'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'un Aug 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:20
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Aug 2020'	System	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2020'	System	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Aug 2020 23:06:20

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Joint dislocation, LLT: Shoulder dislocation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:44:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:44:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
Data point term sent to Coder	System	21 Apr 2021 16:39:52
User entered 'L shoulder dislocation'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
User entered 'UN Apr 2019' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:39:46
User entered 'UN UNK 2019'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
User entered 'No (N)'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
User entered 'UN Apr 2019' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:39:46
User entered 'UN UNK 2019'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:56:46
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Apr 2019'	System	21 Apr 2021 16:39:46
User entered 'Jan 2019'	System	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2019'	System	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Apr 2019'	System	21 Apr 2021 16:39:46
User entered 'Jan 2019'	System	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2019'	System	21 Apr 2021 16:39:17

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:45:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:45:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
Data point term sent to Coder	System	21 Apr 2021 16:39:52
User entered 'L shoulder rotator cuff tear'	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
User entered 'UN Apr 2019'	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:58:37
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered 'Apr 2019'	System	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered '2019'	System	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User entered empty.	System	21 Apr 2021 16:39:34

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '21 Aug 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '17:22'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered '21 Aug 2020 17:22'	System	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '174.7' cm	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04
DataPoint set to visible.	(b) (4) System	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '107.5' kg	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04
DataPoint set to visible.	(b) (4) System	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
Amendment Manager: User entered '35.22270'	System	17 Sep 2020 00:19:30
User entered '35.2'	System	21 Aug 2020 23:09:04
DataPoint set to visible.	System	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered 'kg/m2'	System	21 Aug 2020 23:09:04
DataPoint set to visible.	System	21 Aug 2020 22:58:23

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '36.9' C	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered 'Oral (Oral)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '66'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered 'bpm'	System	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '14'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered 'breaths/min'	System	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '143'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered 'mmHg'	System	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:22
User entered '86'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46
User entered 'mmHg'	System	21 Aug 2020 23:09:04

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46

US3432240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:46

US3432240

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:30
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:16

US3432240

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:30
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:41:14
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		22 Aug 2020 15:34:52
User entered '21 Aug 2020'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:16
	(b) (4)	

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'No (N)'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered 'I'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '0'	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:49:03
User entered empty.	Natalie Izaguirre (b) (4)	21 Aug 2020 23:09:59

US3432240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:34
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 15:34:52

US3432240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:34
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:41
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 15:34:52

US3432240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:34
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:41
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Aug 2020 15:34:52

US3432240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:34
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'VISIT1'	System	22 Aug 2020 15:34:52

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:54:33

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered '187776'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:54:33

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:54:33

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Folder: Visit 1 Day 1

Form: Randomization

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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)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:45:08

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

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)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:45:08

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:45:08

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:45:08

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:02:58
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:45:08

US3432240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:40

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:39
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 03:34:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
User entered 'No (N)'	Bruce Bausk (b) (4)	01 Oct 2020 23:54:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:14:18

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:25
User closed query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. (Site from CRA). Query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' answered with 'height and weight taken on 22Aug. Updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 03:24:31
Query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' answered with 'height and weight taken on 22Aug. Updated' (Site from CRA).	Bruce Bausk (b) (4)	01 Oct 2020 23:54:20
User entered '176' cm reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
User opened query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
User closed query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
Query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' answered with 'updated' (Site from CRA).	Jun Bai Park Chang (b) (4)	15 Sep 2020 18:56:21
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User opened query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 22:04:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:28
User entered '106.7' kg reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:25
User closed query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 03:24:31
Query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' answered with 'height and weight taken on 22Aug. Updated' (Site from CRA).	Bruce Bausk (b) (4)	01 Oct 2020 23:54:20
User entered '176' cm reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
User opened query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
User closed query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
Query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' answered with 'updated' (Site from CRA).	Jun Bai Park Chang (b) (4)	15 Sep 2020 18:56:21
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User opened query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 22:04:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:28
User entered '106.7' kg reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '10:44'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '22 Aug 2020 10:44'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '36.7' C	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '065'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'bpm'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '016'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'breaths/min'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '129'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '086'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:25
User closed query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 03:24:31
Query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' answered with 'height and weight taken on 22Aug. Updated' (Site from CRA).	Bruce Bausk (b) (4)	01 Oct 2020 23:54:20
User entered '176' cm reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
User opened query 'the Day 1 was done on 22Aud, different date from screening (21Aug20), per protocol these assessments are to be done on Day 1 if it is different than Screening day. Please check source as this is marked as done in source. It will be a deviation if this was not done on Day 1. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
User closed query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:00
Query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' answered with 'updated' (Site from CRA).	Jun Bai Park Chang (b) (4)	15 Sep 2020 18:56:21
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:25

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User opened query 'Height and weight- marked as ND- was this not done, but mentioned in source please check and enter.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 22:04:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 03:25:28
User entered '106.7' kg reason for change: Data Entry Error	Bruce Bausk (b) (4)	01 Oct 2020 23:53:55
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '11:54'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '22 Aug 2020 11:54'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '36.7' C	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '066'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'bpm'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '016'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'breaths/min'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '142'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:04:19
User entered '082'	(b) (4), (b) (6)	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	22 Aug 2020 17:48:51

US3432240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:05:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:56:00

US3432240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:05:48
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:56:00

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

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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)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered '11:23'	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '22 Aug 2020 11:23'	System	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:08
User entered 'ONCE'	System	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 15:35:21

US3432240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:59
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:56:25

US3432240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:59
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:17
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:56:25

US3432240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:59
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:17
User entered '11:02'	(b) (4), (b) (6)	22 Aug 2020 17:56:25

US3432240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:52:59
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '22 Aug 2020 11:02'	System	22 Aug 2020 17:56:25

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:25
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:25
User entered '11:10'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '22 Aug 2020 11:10'	System	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:25
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:06:25
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:05
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered empty.	System	22 Aug 2020 17:56:40

US3432240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:09
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 21:40:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:56:44

US3432240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:09
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	22 Aug 2020 17:56:44

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:57:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4132572-4bb6-4805-af3c-289159b3e76d' User entered 'Yes (Y)'	System	22 Aug 2020 15:57:58
	System	22 Aug 2020 15:57:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:57:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4132572-4bb6-4805-af3c-289159b3e76d' User entered '98.1'	System	22 Aug 2020 15:57:58
	System	22 Aug 2020 15:57:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:57:49', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4132572-4bb6-4805-af3c-289159b3e76d'	System	22 Aug 2020 15:57:58
User entered 'No (N)'	System	22 Aug 2020 15:57:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:57:55', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4132572-4bb6-4805-af3c-289159b3e76d' User entered '22 Aug 2020 11:57'	System	22 Aug 2020 15:57:58
	System	22 Aug 2020 15:57:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 11:43'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 14:13'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T20:59:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5fbf2470-8db9-4f09-adba-bfe63b14b208'	System	23 Aug 2020 01:00:45
User entered 'Yes (Y)'	System	23 Aug 2020 01:00:45

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:00:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5fbf2470-8db9-4f09-adba-bfe63b14b208' User entered '97.4'	System	23 Aug 2020 01:00:45
	System	23 Aug 2020 01:00:45

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:00:35', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5fbf2470-8db9-4f09-adba-bfe63b14b208'	System	23 Aug 2020 01:00:45
User entered 'No (N)'	System	23 Aug 2020 01:00:45

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:00:41', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5fbf2470-8db9-4f09-adba-bfe63b14b208'	System	23 Aug 2020 01:00:45
User entered '22 Aug 2020 21:00'	System	23 Aug 2020 01:00:45

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 15:08'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 2'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:09', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '68ef9555-0023-4e6e-aefa-f4789abe4042' User entered 'Yes (Y)'	System	23 Aug 2020 22:02:26
	System	23 Aug 2020 22:02:26

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '68ef9555-0023-4e6e-aefa-f4789abe4042' User entered '97.7'	System	23 Aug 2020 22:02:26
	System	23 Aug 2020 22:02:26

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '68ef9555-0023-4e6e-aefa-f4789abe4042'	System	23 Aug 2020 22:02:26
User entered 'No (N)'	System	23 Aug 2020 22:02:26

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '68ef9555-0023-4e6e-aefa-f4789abe4042'	System	23 Aug 2020 22:02:26
User entered '23 Aug 2020 18:02'	System	23 Aug 2020 22:02:26

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 3'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '94fdf7dc-40d6-4233-bec1-220ef6aacd7f' User entered 'Yes (Y)'	System	24 Aug 2020 23:08:47
	System	24 Aug 2020 23:08:47

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '94fdf7dc-40d6-4233-bec1-220ef6aacd7f' User entered '97.3'	System	24 Aug 2020 23:08:47
	System	24 Aug 2020 23:08:47

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:41', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '94fdf7dc-40d6-4233-bec1-220ef6aacd7f' User entered 'No (N)'	System	24 Aug 2020 23:08:47
	System	24 Aug 2020 23:08:47

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '94fdf7dc-40d6-4233-bec1-220ef6aacd7f' User entered '24 Aug 2020 19:08'	System	24 Aug 2020 23:08:47
	System	24 Aug 2020 23:08:47

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 4'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:46:33', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd5cc3f72-7da6-4718-8adc-9a552c2b1f8d' User entered 'Yes (Y)'	System	26 Aug 2020 02:47:23
	System	26 Aug 2020 02:47:23

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd5cc3f72-7da6-4718-8adc-9a552c2b1f8d' User entered '96.9'	System	26 Aug 2020 02:47:23
	System	26 Aug 2020 02:47:23

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd5cc3f72-7da6-4718-8adc-9a552c2b1f8d'	System	26 Aug 2020 02:47:23
User entered 'No (N)'	System	26 Aug 2020 02:47:23

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd5cc3f72-7da6-4718-8adc-9a552c2b1f8d' User entered '25 Aug 2020 22:47'	System	26 Aug 2020 02:47:23
	System	26 Aug 2020 02:47:23

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 5'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '128daf41-4910-489e-a01e-28ccb80eb735'	System	26 Aug 2020 22:09:42
User entered 'Yes (Y)'	System	26 Aug 2020 22:09:42

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:33', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '128daf41-4910-489e-a01e-28ccb80eb735' User entered '96.8'	System	26 Aug 2020 22:09:42
	System	26 Aug 2020 22:09:42

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '128daf41-4910-489e-a01e-28ccb80eb735'	System	26 Aug 2020 22:09:42
User entered 'No (N)'	System	26 Aug 2020 22:09:42

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:40', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '128daf41-4910-489e-a01e-28ccb80eb735' User entered '26 Aug 2020 18:09'	System	26 Aug 2020 22:09:42
	System	26 Aug 2020 22:09:42

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 6'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:15:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e1b7c01b-d459-4865-8c57-5f6837252c3a' User entered 'Yes (Y)'	System	28 Aug 2020 00:15:58
	System	28 Aug 2020 00:15:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:15:48', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e1b7c01b-d459-4865-8c57-5f6837252c3a' User entered '95.2'	System	28 Aug 2020 00:15:58
	System	28 Aug 2020 00:15:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:15:51', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e1b7c01b-d459-4865-8c57-5f6837252c3a' User entered 'No (N)'	System	28 Aug 2020 00:15:58
	System	28 Aug 2020 00:15:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:15:54', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e1b7c01b-d459-4865-8c57-5f6837252c3a' User entered '27 Aug 2020 20:15'	System	28 Aug 2020 00:15:58
	System	28 Aug 2020 00:15:58

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 7'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5678d65d-74cf-491a-9ea0-147ac7ba34ae' User entered 'Yes (Y)'	System	28 Aug 2020 18:32:34
	System	28 Aug 2020 18:32:34

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5678d65d-74cf-491a-9ea0-147ac7ba34ae' User entered '96.2'	System	28 Aug 2020 18:32:34
	System	28 Aug 2020 18:32:34

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:27', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5678d65d-74cf-491a-9ea0-147ac7ba34ae' User entered 'No (N)'	System	28 Aug 2020 18:32:34
	System	28 Aug 2020 18:32:34

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5678d65d-74cf-491a-9ea0-147ac7ba34ae' User entered '28 Aug 2020 14:32'	System	28 Aug 2020 18:32:34
	System	28 Aug 2020 18:32:34

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:58:22', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63156cb0-f7cf-4915-bc80-c7edf83119b2'	System	22 Aug 2020 15:59:12
User entered 'None (1)'	System	22 Aug 2020 15:59:12

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:58:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63156cb0-f7cf-4915-bc80-c7edf83119b2'	System	22 Aug 2020 15:59:12
User entered 'No (N)'	System	22 Aug 2020 15:59:12

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:58:53', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63156cb0-f7cf-4915-bc80-c7edf83119b2'	System	22 Aug 2020 15:59:12
User entered 'No (N)'	System	22 Aug 2020 15:59:12

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63156cb0-f7cf-4915-bc80-c7edf83119b2'	System	22 Aug 2020 15:59:12
User entered 'None (1)'	System	22 Aug 2020 15:59:12

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:09', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63156cb0-f7cf-4915-bc80-c7edf83119b2'	System	22 Aug 2020 15:59:12
User entered '22 Aug 2020 11:59'	System	22 Aug 2020 15:59:12

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 11:43'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 14:13'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:00:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c2f9fd7e-506b-4b4e-9326-422a816cf30a' User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 01:02:21
	System	23 Aug 2020 01:02:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:01:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c2f9fd7e-506b-4b4e-9326-422a816cf30a' User entered 'No (N)'	System	23 Aug 2020 01:02:21
	System	23 Aug 2020 01:02:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:01:58', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c2f9fd7e-506b-4b4e-9326-422a816cf30a' User entered 'No (N)'	System	23 Aug 2020 01:02:21
	System	23 Aug 2020 01:02:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c2f9fd7e-506b-4b4e-9326-422a816cf30a' User entered 'None (1)'	System	23 Aug 2020 01:02:21
	System	23 Aug 2020 01:02:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c2f9fd7e-506b-4b4e-9326-422a816cf30a' User entered '22 Aug 2020 21:02'	System	23 Aug 2020 01:02:21
	System	23 Aug 2020 01:02:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 15:08'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 2'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '197d75b1-6778-4e9f-ac32-21c39094ee3f' User entered 'None (1)'	System	23 Aug 2020 22:03:04
	System	23 Aug 2020 22:03:04

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '197d75b1-6778-4e9f-ac32-21c39094ee3f' User entered 'No (N)'	System	23 Aug 2020 22:03:04
	System	23 Aug 2020 22:03:04

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:48', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '197d75b1-6778-4e9f-ac32-21c39094ee3f' User entered 'No (N)'	System	23 Aug 2020 22:03:04
	System	23 Aug 2020 22:03:04

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:02:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '197d75b1-6778-4e9f-ac32-21c39094ee3f' User entered 'None (1)'	System	23 Aug 2020 22:03:04
	System	23 Aug 2020 22:03:04

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '197d75b1-6778-4e9f-ac32-21c39094ee3f' User entered '23 Aug 2020 18:03'	System	23 Aug 2020 22:03:04
	System	23 Aug 2020 22:03:04

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 3'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '253eb777-4987-463a-8458-2e5f53fe17e8' User entered 'None (1)'	System	24 Aug 2020 23:09:18
	System	24 Aug 2020 23:09:18

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:08:54', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '253eb777-4987-463a-8458-2e5f53fe17e8' User entered 'No (N)'	System	24 Aug 2020 23:09:18
	System	24 Aug 2020 23:09:18

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '253eb777-4987-463a-8458-2e5f53fe17e8' User entered 'No (N)'	System	24 Aug 2020 23:09:18
	System	24 Aug 2020 23:09:18

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '253eb777-4987-463a-8458-2e5f53fe17e8' User entered 'None (1)'	System	24 Aug 2020 23:09:18
	System	24 Aug 2020 23:09:18

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:16', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '253eb777-4987-463a-8458-2e5f53fe17e8' User entered '24 Aug 2020 19:09'	System	24 Aug 2020 23:09:18
	System	24 Aug 2020 23:09:18

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 4'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:27', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0c3db0de-f79b-4156-9b23-48d02ae6a401' User entered 'None (1)'	System	26 Aug 2020 02:47:47
	System	26 Aug 2020 02:47:47

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0c3db0de-f79b-4156-9b23-48d02ae6a401' User entered 'No (N)'	System	26 Aug 2020 02:47:47
	System	26 Aug 2020 02:47:47

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:35', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0c3db0de-f79b-4156-9b23-48d02ae6a401' User entered 'No (N)'	System	26 Aug 2020 02:47:47
	System	26 Aug 2020 02:47:47

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0c3db0de-f79b-4156-9b23-48d02ae6a401' User entered 'None (1)'	System	26 Aug 2020 02:47:47
	System	26 Aug 2020 02:47:47

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0c3db0de-f79b-4156-9b23-48d02ae6a401' User entered '25 Aug 2020 22:47'	System	26 Aug 2020 02:47:47
	System	26 Aug 2020 02:47:47

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 5'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2a44a464-6b8b-46f1-be51-cca8fe90b767'	System	26 Aug 2020 22:10:09
User entered 'None (1)'	System	26 Aug 2020 22:10:09

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:49', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2a44a464-6b8b-46f1-be51-cca8fe90b767'	System	26 Aug 2020 22:10:09
User entered 'No (N)'	System	26 Aug 2020 22:10:09

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:09:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2a44a464-6b8b-46f1-be51-cca8fe90b767'	System	26 Aug 2020 22:10:09
User entered 'No (N)'	System	26 Aug 2020 22:10:09

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2a44a464-6b8b-46f1-be51-cca8fe90b767'	System	26 Aug 2020 22:10:09
User entered 'None (1)'	System	26 Aug 2020 22:10:09

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:08', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2a44a464-6b8b-46f1-be51-cca8fe90b767'	System	26 Aug 2020 22:10:09
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 22:10:09

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 6'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:15:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4fad702-6431-4b7f-ad51-30593b66bd9a' User entered 'None (1)'	System	28 Aug 2020 00:16:20
	System	28 Aug 2020 00:16:20

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4fad702-6431-4b7f-ad51-30593b66bd9a' User entered 'No (N)'	System	28 Aug 2020 00:16:20
	System	28 Aug 2020 00:16:20

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4fad702-6431-4b7f-ad51-30593b66bd9a' User entered 'No (N)'	System	28 Aug 2020 00:16:20
	System	28 Aug 2020 00:16:20

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:15', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4fad702-6431-4b7f-ad51-30593b66bd9a' User entered 'None (1)'	System	28 Aug 2020 00:16:20
	System	28 Aug 2020 00:16:20

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a4fad702-6431-4b7f-ad51-30593b66bd9a' User entered '27 Aug 2020 20:16'	System	28 Aug 2020 00:16:20
	System	28 Aug 2020 00:16:20

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 7'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:35', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bf19df04-0f79-458c-bd42-0593b2fde9ec' User entered 'None (1)'	System	28 Aug 2020 18:33:10
	System	28 Aug 2020 18:33:10

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:47', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bf19df04-0f79-458c-bd42-0593b2fde9ec'	System	28 Aug 2020 18:33:10
User entered 'No (N)'	System	28 Aug 2020 18:33:10

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:32:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bf19df04-0f79-458c-bd42-0593b2fde9ec'	System	28 Aug 2020 18:33:10
User entered 'No (N)'	System	28 Aug 2020 18:33:10

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bf19df04-0f79-458c-bd42-0593b2fde9ec' User entered 'None (1)'	System	28 Aug 2020 18:33:10
	System	28 Aug 2020 18:33:10

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bf19df04-0f79-458c-bd42-0593b2fde9ec'	System	28 Aug 2020 18:33:10
User entered '28 Aug 2020 14:33'	System	28 Aug 2020 18:33:10

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:28', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'None (0)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered 'No (N)'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T11:59:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f20edad0-da58-4ffa-b871-7ea8be3ea5fd' User entered '22 Aug 2020 11:59'	System	22 Aug 2020 15:59:39
	System	22 Aug 2020 15:59:39

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 11:43'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 14:13'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77' User entered 'None (0)'	System	23 Aug 2020 01:02:51
	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:26', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77' User entered 'None (0)'	System	23 Aug 2020 01:02:51
	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77' User entered 'None (0)'	System	23 Aug 2020 01:02:51
	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:33', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77' User entered 'None (0)'	System	23 Aug 2020 01:02:51
	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77' User entered 'None (0)'	System	23 Aug 2020 01:02:51
	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:39', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77'	System	23 Aug 2020 01:02:51
User entered 'None (0)'	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:44', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77'	System	23 Aug 2020 01:02:51
User entered 'No (N)'	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-22T21:02:49', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1cdb8634-7ea8-4861-b48d-517173339f77'	System	23 Aug 2020 01:02:51
User entered '22 Aug 2020 21:02'	System	23 Aug 2020 01:02:51

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '22 Aug 2020 15:08'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 2'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:06', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:16', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:19', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'None (0)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:27', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered 'No (N)'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-23T18:03:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '255457d8-62d7-4f8f-9c27-9835a4b787d5' User entered '23 Aug 2020 18:03'	System	23 Aug 2020 22:03:35
	System	23 Aug 2020 22:03:35

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 3'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:26', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:29', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'None (0)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:51', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered 'No (N)'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-24T19:09:54', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c3f9193f-83de-44d2-a820-02d65d316689' User entered '24 Aug 2020 19:09'	System	24 Aug 2020 23:09:56
	System	24 Aug 2020 23:09:56

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 4'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:52', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e'	System	26 Aug 2020 02:48:17
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:55', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'None (0)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:47:58', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'None (0)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:48:01', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'None (0)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:48:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'None (0)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:48:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'None (0)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:48:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered 'No (N)'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-25T22:48:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '359750cb-3d7e-4d33-b52c-dd5f06c11e2e' User entered '25 Aug 2020 22:48'	System	26 Aug 2020 02:48:17
	System	26 Aug 2020 02:48:17

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 5'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:16', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:19', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:22', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'None (0)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:28', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered 'No (N)'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-26T18:10:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '2858daa5-5b33-46d0-b98e-2fbfa56936d4' User entered '26 Aug 2020 18:10'	System	26 Aug 2020 22:10:34
	System	26 Aug 2020 22:10:34

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 6'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:26', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:28', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'None (0)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered 'No (N)'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-27T20:16:39', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0eb225fa-cfba-4d6a-a807-22b5ee840564' User entered '27 Aug 2020 20:16'	System	28 Aug 2020 00:16:41
	System	28 Aug 2020 00:16:41

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 7'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:12', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:16', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'None (0)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:27', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered 'No (N)'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-08-28T14:33:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '8616ab74-8ecf-4892-9a68-a5980c783868' User entered '28 Aug 2020 14:33'	System	28 Aug 2020 18:33:37
	System	28 Aug 2020 18:33:37

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:35:21

US3432240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:15
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:07:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 18:45:51

US3432240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:15
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:07:45
User entered '29 Aug 2020'	Julia Klopfer (b) (4)	29 Aug 2020 18:45:51

US3432240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:15
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:07:45
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4)	29 Aug 2020 18:45:51

US3432240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:15
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:07:45
User entered empty.	Julia Klopfer (b) (4)	29 Aug 2020 18:45:51

US3432240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:20
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:07:54
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 18:45:55

US3432240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:20
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	29 Aug 2020 18:45:55

US3432240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:25
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 16:29:16

US3432240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:25
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:36
User entered '5 Sep 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 16:29:16

US3432240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:25
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:36
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	05 Sep 2020 16:29:16

US3432240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:25
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:36
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 16:29:16

US3432240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:31
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 16:29:20

US3432240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:31
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	05 Sep 2020 16:29:20

US3432240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:36
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 13:56:22

US3432240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:36
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:15
User entered '12 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 13:56:22

US3432240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:36
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Sep 2020 13:56:22

US3432240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:36
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:15
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 13:56:22

US3432240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:41
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 13:56:26

US3432240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:41
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	12 Sep 2020 13:56:26

US3432240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:46
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:50:54

US3432240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:46
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:23
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:50:54

US3432240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:46
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Sep 2020 17:50:54

US3432240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:46
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'VISIT2'	System	25 Sep 2020 17:50:54

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '10:41'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '25 Sep 2020 10:41'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '036.6' C	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '060'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'bpm'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '012'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'breaths/min'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '147'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '081'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '11:44'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '25 Sep 2020 11:44'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '036.6' C	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '054'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'bpm'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '020'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'breaths/min'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '133'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:08
User entered '081'	(b) (4), (b) (6)	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:50
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	25 Sep 2020 17:55:14

US3432240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:55
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:20

US3432240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:53:55
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:11
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:55:20

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered '11:13'	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '25 Sep 2020 11:13'	System	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:20
User entered 'ONCE'	System	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:40
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 15:50:03

US3432240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:36

US3432240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:30
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:55:36

US3432240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:30
User entered '10:58'	(b) (4), (b) (6)	25 Sep 2020 17:55:36

US3432240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:45
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '25 Sep 2020 10:58'	System	25 Sep 2020 17:55:36

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:36
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:36
User entered '11:02'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '25 Sep 2020 11:02'	System	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:36
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:36
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:54
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered empty.	System	25 Sep 2020 17:55:51

US3432240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:55:56

US3432240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:54:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	25 Sep 2020 17:55:56

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:22', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267' User entered 'Yes (Y)'	System	25 Sep 2020 15:50:53
	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:29', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267' User entered '97.9'	System	25 Sep 2020 15:50:53
	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267'	System	25 Sep 2020 15:50:53
User entered 'Yes (Y)'	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:22:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Alexander Mills (b) (4)	18 Nov 2020 21:33:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267'	System	25 Sep 2020 15:50:53
User entered '1'	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267' User entered '0'	System	25 Sep 2020 15:50:53
	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0417c2c4-168e-4d96-a29b-d1827009e267' User entered '25 Sep 2020 11:50'	System	25 Sep 2020 15:50:53
	System	25 Sep 2020 15:50:53

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 11:33'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:03'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:58'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 2'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266' User entered 'Yes (Y)'	System	26 Sep 2020 22:14:36
	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266' User entered '98.9'	System	26 Sep 2020 22:14:36
	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266'	System	26 Sep 2020 22:14:36
User entered 'Yes (Y)'	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:23:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266'	Alexander Mills (b) (4)	18 Nov 2020 21:33:52
User entered '1'	System	26 Sep 2020 22:14:36
	System	26 Sep 2020 22:14:36
	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266' User entered '0'	System	26 Sep 2020 22:14:36
	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:14:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '963372b2-84ac-47f4-bfb0-7a286ab79266'	System	26 Sep 2020 22:14:36
User entered '26 Sep 2020 18:14'	System	26 Sep 2020 22:14:36

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 3'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e' User entered 'Yes (Y)'	System	26 Sep 2020 00:53:34
	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:38', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e' User entered '96.9'	System	26 Sep 2020 00:53:34
	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e' User entered 'Yes (Y)'	System	26 Sep 2020 00:53:34
	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:23:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Alexander Mills (b) (4)	18 Nov 2020 21:34:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:51', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e'	System	26 Sep 2020 00:53:34
User entered '1'	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:51', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e' User entered '0'	System	26 Sep 2020 00:53:34
	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:52:55', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '7aea401b-a495-4b42-b172-d260e2b49d6e' User entered '27 Sep 2020 20:52'	System	26 Sep 2020 00:53:34
	System	26 Sep 2020 00:53:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 4'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:01', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered 'Yes (Y)'	System	28 Sep 2020 20:25:21
	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered '97.6'	System	28 Sep 2020 20:25:21
	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765'	System	28 Sep 2020 20:25:21
User entered 'Yes (Y)'	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:23:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:15', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered '1'	Alexander Mills (b) (4)	18 Nov 2020 21:34:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Sep 2020 20:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:15', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered '1'	System	28 Sep 2020 20:25:21
User entered '1'	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:15', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered '0'	System	28 Sep 2020 20:25:21
	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd89bf3f1-a8cc-4467-a49a-9aa3c6d52765' User entered '28 Sep 2020 16:25'	System	28 Sep 2020 20:25:21
	System	28 Sep 2020 20:25:21

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 5'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:12', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84' User entered 'No (N)'	System	30 Sep 2020 01:02:34
	System	30 Sep 2020 01:02:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84'	System	30 Sep 2020 01:02:34
User entered 'Yes (Y)'	System	30 Sep 2020 01:02:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:23:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84' User entered '1'	Alexander Mills (b) (4)	18 Nov 2020 21:34:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Sep 2020 01:02:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84' User entered '1'	System	30 Sep 2020 01:02:34
User entered '1'	System	30 Sep 2020 01:02:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84' User entered '0'	System	30 Sep 2020 01:02:34
	System	30 Sep 2020 01:02:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:29', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd00fbc10-d839-4ab3-87dd-84ce312e6b84' User entered '29 Sep 2020 21:02'	System	30 Sep 2020 01:02:34
	System	30 Sep 2020 01:02:34

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 6'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3' User entered 'No (N)'	System	01 Oct 2020 02:40:18
	System	01 Oct 2020 02:40:18

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3'	System	01 Oct 2020 02:40:18
User entered 'Yes (Y)'	System	01 Oct 2020 02:40:18

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 18:23:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3' User entered '1'	Alexander Mills (b) (4)	18 Nov 2020 21:34:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 02:40:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3' User entered '1'	System	01 Oct 2020 02:40:18
User entered '1'	System	01 Oct 2020 02:40:18

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3' User entered '0'	System	01 Oct 2020 02:40:18
	System	01 Oct 2020 02:40:18

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c9f4cabf-928b-48ec-8e27-0adcfc8939a3' User entered '30 Sep 2020 22:40'	System	01 Oct 2020 02:40:18
	System	01 Oct 2020 02:40:18

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 7'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c74c3b4e-7470-4c9a-abb3-58306ba8a263' User entered 'No (N)'	System	02 Oct 2020 09:48:52
	System	02 Oct 2020 09:48:52

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:38', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c74c3b4e-7470-4c9a-abb3-58306ba8a263'	System	02 Oct 2020 09:48:52
User entered 'Yes (Y)'	System	02 Oct 2020 09:48:52

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication captured in concomitant medication for dental procedure' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 15:31:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c74c3b4e-7470-4c9a-abb3-58306ba8a263' User entered '1'	Alexander Mills (b) (4)	18 Nov 2020 21:35:01
	System	02 Oct 2020 09:48:52
	System	02 Oct 2020 09:48:52
	System	02 Oct 2020 09:48:52

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c74c3b4e-7470-4c9a-abb3-58306ba8a263' User entered '0'	System	02 Oct 2020 09:48:52
	System	02 Oct 2020 09:48:52

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:48', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c74c3b4e-7470-4c9a-abb3-58306ba8a263' User entered '02 Oct 2020 05:48'	System	02 Oct 2020 09:48:52
	System	02 Oct 2020 09:48:52

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:50:56', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '13850bb5-a2d2-4720-b652-c01d7a7ab60d' User entered 'None (1)'	System	25 Sep 2020 15:51:18
	System	25 Sep 2020 15:51:18

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '13850bb5-a2d2-4720-b652-c01d7a7ab60d' User entered 'No (N)'	System	25 Sep 2020 15:51:18
	System	25 Sep 2020 15:51:18

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:06', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '13850bb5-a2d2-4720-b652-c01d7a7ab60d' User entered 'No (N)'	System	25 Sep 2020 15:51:18
	System	25 Sep 2020 15:51:18

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '13850bb5-a2d2-4720-b652-c01d7a7ab60d' User entered 'None (1)'	System	25 Sep 2020 15:51:18
	System	25 Sep 2020 15:51:18

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '13850bb5-a2d2-4720-b652-c01d7a7ab60d' User entered '25 Sep 2020 11:51'	System	25 Sep 2020 15:51:18
	System	25 Sep 2020 15:51:18

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 11:33'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:03'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:58'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 2'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77'	System	26 Sep 2020 22:15:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:09', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77'	System	26 Sep 2020 22:15:42
User entered 'No (N)'	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77' User entered 'Yes (Y)'	System	26 Sep 2020 22:15:42
	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77' User entered '55'	System	26 Sep 2020 22:15:42
	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:30', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77' User entered 'None (1)'	System	26 Sep 2020 22:15:42
	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:41', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e389270-c84f-448a-a7ff-dde1a7a9cd77' User entered '26 Sep 2020 18:15'	System	26 Sep 2020 22:15:42
	System	26 Sep 2020 22:15:42

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 3'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '162593cd-5898-4035-8acf-717ed9b2bb8f' User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 00:54:15
	System	26 Sep 2020 00:54:15

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '162593cd-5898-4035-8acf-717ed9b2bb8f' User entered 'No (N)'	System	26 Sep 2020 00:54:15
	System	26 Sep 2020 00:54:15

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '162593cd-5898-4035-8acf-717ed9b2bb8f' User entered 'No (N)'	System	26 Sep 2020 00:54:15
	System	26 Sep 2020 00:54:15

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '162593cd-5898-4035-8acf-717ed9b2bb8f' User entered 'None (1)'	System	26 Sep 2020 00:54:15
	System	26 Sep 2020 00:54:15

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '162593cd-5898-4035-8acf-717ed9b2bb8f' User entered '27 Sep 2020 20:53'	System	26 Sep 2020 00:54:15
	System	26 Sep 2020 00:54:15

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 4'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:28', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c'	System	28 Sep 2020 20:26:20
User entered 'None (1)'	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:44', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c'	System	28 Sep 2020 20:26:20
User entered 'No (N)'	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:25:48', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c' User entered 'Yes (Y)'	System	28 Sep 2020 20:26:20
	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c' User entered '5'	System	28 Sep 2020 20:26:20
	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c'	System	28 Sep 2020 20:26:20
User entered 'None (1)'	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'a081fb1f-f244-4263-9ebf-a4ca8adc1b5c'	System	28 Sep 2020 20:26:20
User entered '28 Sep 2020 16:26'	System	28 Sep 2020 20:26:20

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 5'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:35', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6ea3e2d0-5ff1-474e-a899-8c58b87198c3' User entered 'None (1)'	System	30 Sep 2020 01:02:51
	System	30 Sep 2020 01:02:51

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:38', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6ea3e2d0-5ff1-474e-a899-8c58b87198c3' User entered 'No (N)'	System	30 Sep 2020 01:02:51
	System	30 Sep 2020 01:02:51

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:41', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6ea3e2d0-5ff1-474e-a899-8c58b87198c3' User entered 'No (N)'	System	30 Sep 2020 01:02:51
	System	30 Sep 2020 01:02:51

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:44', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6ea3e2d0-5ff1-474e-a899-8c58b87198c3' User entered 'None (1)'	System	30 Sep 2020 01:02:51
	System	30 Sep 2020 01:02:51

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:46', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6ea3e2d0-5ff1-474e-a899-8c58b87198c3' User entered '29 Sep 2020 21:02'	System	30 Sep 2020 01:02:51
	System	30 Sep 2020 01:02:51

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 6'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5e544df7-c81e-4852-a708-e9b1df7f4c15'	System	01 Oct 2020 02:40:38
User entered 'None (1)'	System	01 Oct 2020 02:40:38

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5e544df7-c81e-4852-a708-e9b1df7f4c15'	System	01 Oct 2020 02:40:38
User entered 'No (N)'	System	01 Oct 2020 02:40:38

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:24', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5e544df7-c81e-4852-a708-e9b1df7f4c15'	System	01 Oct 2020 02:40:38
User entered 'No (N)'	System	01 Oct 2020 02:40:38

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5e544df7-c81e-4852-a708-e9b1df7f4c15'	System	01 Oct 2020 02:40:38
User entered 'None (1)'	System	01 Oct 2020 02:40:38

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5e544df7-c81e-4852-a708-e9b1df7f4c15' User entered '30 Sep 2020 22:40'	System	01 Oct 2020 02:40:38
	System	01 Oct 2020 02:40:38

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 7'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:54', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd1e6e0fe-6cab-411a-a687-8063cc29b05e' User entered 'None (1)'	System	02 Oct 2020 09:49:09
	System	02 Oct 2020 09:49:09

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:48:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd1e6e0fe-6cab-411a-a687-8063cc29b05e' User entered 'No (N)'	System	02 Oct 2020 09:49:09
	System	02 Oct 2020 09:49:09

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd1e6e0fe-6cab-411a-a687-8063cc29b05e' User entered 'No (N)'	System	02 Oct 2020 09:49:09
	System	02 Oct 2020 09:49:09

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd1e6e0fe-6cab-411a-a687-8063cc29b05e' User entered 'None (1)'	System	02 Oct 2020 09:49:09
	System	02 Oct 2020 09:49:09

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:07', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd1e6e0fe-6cab-411a-a687-8063cc29b05e' User entered '02 Oct 2020 05:49'	System	02 Oct 2020 09:49:09
	System	02 Oct 2020 09:49:09

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:29', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered 'None (0)'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5'	System	25 Sep 2020 15:51:40
User entered 'No (N)'	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-25T11:51:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1808558f-0821-49dd-9c8e-1b1f6bfa00f5' User entered '25 Sep 2020 11:51'	System	25 Sep 2020 15:51:40
	System	25 Sep 2020 15:51:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 11:33'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:03'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '25 Sep 2020 14:58'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 2'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:15:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8'	System	26 Sep 2020 22:16:27
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'None (0)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'None (0)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:08', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'None (0)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:11', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'None (0)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'None (0)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:19', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered 'No (N)'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-26T18:16:22', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '436de0f4-93d1-46c9-922f-156452fdede8' User entered '26 Sep 2020 18:16'	System	26 Sep 2020 22:16:27
	System	26 Sep 2020 22:16:27

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 3'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:39', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:47', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:49', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:52', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'None (0)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:53:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered 'No (N)'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-27T20:54:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c1f560f0-314b-4a5a-aa1c-0bd1f2a4524e' User entered '27 Sep 2020 20:54'	System	26 Sep 2020 00:54:40
	System	26 Sep 2020 00:54:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 4'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:38', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:40', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:43', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:47', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered 'None (0)'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:53', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0'	System	28 Sep 2020 20:26:59
User entered 'No (N)'	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-28T16:26:56', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ef6630e8-949f-471b-aba0-7e2d29ead7f0' User entered '28 Sep 2020 16:26'	System	28 Sep 2020 20:26:59
	System	28 Sep 2020 20:26:59

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 5'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:53', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:55', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:57', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:02:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:03:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:03:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'None (0)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:03:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered 'No (N)'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-29T21:03:16', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd3a3124f-e906-4dd2-ad5d-6619554acafb' User entered '29 Sep 2020 21:03'	System	30 Sep 2020 01:03:38
	System	30 Sep 2020 01:03:38

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 6'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:40', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:48', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:53', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered 'None (0)'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:40:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95'	System	01 Oct 2020 02:41:07
User entered 'Yes (Y)'	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-09-30T22:41:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e3c38a58-a613-4660-bf67-e22bbafc5f95' User entered '30 Sep 2020 22:41'	System	01 Oct 2020 02:41:07
	System	01 Oct 2020 02:41:07

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	25 Sep 2020 15:50:03
User entered 'Day 7'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:15', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'None (0)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered 'No (N)'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-02T05:49:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63ea8a8a-45ae-4437-bfba-9aea24fb2a29' User entered '02 Oct 2020 05:49'	System	02 Oct 2020 09:49:40
	System	02 Oct 2020 09:49:40

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:50:03

US3432240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:50:03

US3432240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:04
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:18:09

US3432240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:04
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:09
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:18:09

US3432240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:04
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 14:18:09

US3432240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:04
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:09
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:18:09

US3432240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:08
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:18:14

US3432240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:08
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	02 Oct 2020 14:18:14

US3432240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:13
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:15:18

US3432240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:13
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:14
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:15:18

US3432240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:13
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 14:15:18

US3432240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:13
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:14
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:15:18

US3432240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:17
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:15:23

US3432240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:17
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	09 Oct 2020 14:15:23

US3432240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:23
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:18:26

US3432240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:23
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:20
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:18:26

US3432240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:23
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 14:18:26

US3432240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:23
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:18:26

US3432240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:27
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:18:33

US3432240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:27
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	16 Oct 2020 14:18:33

US3432240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:33
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:47:44
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 18:12:14

US3432240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:33
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:47:44
User entered '28 Oct 2020'	Julia Klopfer (b) (4)	28 Oct 2020 18:12:14

US3432240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:33
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:47:44
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	28 Oct 2020 18:12:14

US3432240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:33
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'VISIT3'	System	28 Oct 2020 18:12:14

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '28 Oct 2020'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '12:38' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 21:40:18
User entered '12:32'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '28 Oct 2020 12:38'	System	02 Nov 2020 21:40:18
User entered '28 Oct 2020 12:32'	System	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '37.0' C	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '67'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'bpm'	System	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '16'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'breaths/min'	System	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '128'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:19
User entered '77'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'mmHg'	System	28 Oct 2020 18:13:37

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08

US3432240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:38
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08

US3432240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:42
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:23
User entered 'No (N)'	Julia Klopfer (b) (4)	28 Oct 2020 18:13:41

US3432240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:42
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:48:23
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:13:41

US3432240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:47
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:56:05
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:37:22
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' answered with 'PPD reports this was received.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 15:47:44
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:38:46
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 18:14:07

US3432240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:47
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:56:05
User entered '28 Oct 2020'	Julia Klopfer (b) (4)	28 Oct 2020 18:14:07

US3432240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:47
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:56:05
User entered '12:46'	Julia Klopfer (b) (4)	28 Oct 2020 18:14:07

US3432240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:47
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered '28 Oct 2020 12:46'	System	28 Oct 2020 18:14:07

US3432240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:53
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:26
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:56:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 18:14:16

US3432240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:53
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	28 Oct 2020 18:14:16

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 64'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-22T04:51:44', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '45bd8953-86ea-4f75-8284-94a4b7ba9549' User entered 'No (N)'	System	22 Oct 2020 08:52:03
	System	22 Oct 2020 08:52:03

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-22T04:51:51', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '45bd8953-86ea-4f75-8284-94a4b7ba9549'	System	22 Oct 2020 08:52:03
User entered 'No (N)'	System	22 Oct 2020 08:52:03

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-22T04:52:01', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '45bd8953-86ea-4f75-8284-94a4b7ba9549' User entered '22 Oct 2020 04:52:01'	System	22 Oct 2020 08:52:03
	System	22 Oct 2020 08:52:03

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 71'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-29T04:46:08', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c7923e5c-ffcc-4670-b2b6-d1347a461c29' User entered 'No (N)'	System	29 Oct 2020 08:46:25
	System	29 Oct 2020 08:46:25

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-29T04:46:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c7923e5c-ffcc-4670-b2b6-d1347a461c29'	System	29 Oct 2020 08:46:25
User entered 'No (N)'	System	29 Oct 2020 08:46:25

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-10-29T04:46:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'c7923e5c-ffcc-4670-b2b6-d1347a461c29' User entered '29 Oct 2020 04:46:23'	System	29 Oct 2020 08:46:25
	System	29 Oct 2020 08:46:25

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 78'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-08T17:59:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0133626e-421c-4164-adc3-6f74e153002c' User entered 'No (N)'	System	08 Nov 2020 22:59:26
	System	08 Nov 2020 22:59:26

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-08T17:59:21', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0133626e-421c-4164-adc3-6f74e153002c' User entered 'No (N)'	System	08 Nov 2020 22:59:26
	System	08 Nov 2020 22:59:26

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-08T17:59:25', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0133626e-421c-4164-adc3-6f74e153002c' User entered '08 Nov 2020 17:59:25'	System	08 Nov 2020 22:59:26
	System	08 Nov 2020 22:59:26

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:45
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51
Data entry locked.	System	22 Aug 2020 15:35:21
User entered 'Day 92'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Please 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)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Please 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)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Please 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)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 15:35:21

US3432240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:05:51
Data entry locked.	System	22 Aug 2020 15:35:21
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 15:35:21

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-20T14:44:27', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e978860-87c3-4acd-85d5-f6be5dc8a950'	System	20 Nov 2020 19:44:46
User entered 'No (N)'	System	20 Nov 2020 19:44:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-20T14:44:32', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e978860-87c3-4acd-85d5-f6be5dc8a950'	System	20 Nov 2020 19:44:46
User entered 'No (N)'	System	20 Nov 2020 19:44:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-20T14:44:39', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '0e978860-87c3-4acd-85d5-f6be5dc8a950' User entered '20 Nov 2020 14:44:39'	System	20 Nov 2020 19:44:46
	System	20 Nov 2020 19:44:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-23T04:57:56', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'eed90f5a-7ed8-4e70-ab18-92a75f1fc94e'	System	23 Nov 2020 09:58:12
User entered 'No (N)'	System	23 Nov 2020 09:58:12

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-23T04:58:02', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'eed90f5a-7ed8-4e70-ab18-92a75f1fc94e'	System	23 Nov 2020 09:58:12
User entered 'No (N)'	System	23 Nov 2020 09:58:12

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-11-23T04:58:08', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'eed90f5a-7ed8-4e70-ab18-92a75f1fc94e' User entered '23 Nov 2020 04:58:08'	System	23 Nov 2020 09:58:12
	System	23 Nov 2020 09:58:12

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-02T12:00:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd55fbdc8-9e62-4662-94e5-43d4e343e96c' User entered 'No (N)'	System	02 Dec 2020 17:00:40
	System	02 Dec 2020 17:00:40

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-02T12:00:26', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd55fbdc8-9e62-4662-94e5-43d4e343e96c' User entered 'No (N)'	System	02 Dec 2020 17:00:40
	System	02 Dec 2020 17:00:40

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-02T12:00:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'd55fdbc8-9e62-4662-94e5-43d4e343e96c' User entered '02 Dec 2020 12:00:31'	System	02 Dec 2020 17:00:40
	System	02 Dec 2020 17:00:40

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-07T04:38:09', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'b55697b2-63c7-4096-b2c9-fccf933af738' User entered 'No (N)'	System	07 Dec 2020 09:38:21
	System	07 Dec 2020 09:38:21

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-07T04:38:13', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'b55697b2-63c7-4096-b2c9-fccf933af738'	System	07 Dec 2020 09:38:21
User entered 'No (N)'	System	07 Dec 2020 09:38:21

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-07T04:38:17', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'b55697b2-63c7-4096-b2c9-fccf933af738' User entered '07 Dec 2020 04:38:17'	System	07 Dec 2020 09:38:21
	System	07 Dec 2020 09:38:21

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-14T03:16:49', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1bff1fcb-47da-4eb5-8adc-81cbc1c97a7e'	System	14 Dec 2020 08:17:05
User entered 'No (N)'	System	14 Dec 2020 08:17:05

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-14T03:16:54', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1bff1fcb-47da-4eb5-8adc-81cbc1c97a7e'	System	14 Dec 2020 08:17:05
User entered 'No (N)'	System	14 Dec 2020 08:17:05

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-14T03:16:59', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1bff1fcb-47da-4eb5-8adc-81cbc1c97a7e' User entered '14 Dec 2020 03:16:59'	System	14 Dec 2020 08:17:05
	System	14 Dec 2020 08:17:05

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-21T05:07:06', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '91eb38b9-e21a-4dc9-adab-110261feb54f' User entered 'No (N)'	System	21 Dec 2020 10:07:19
	System	21 Dec 2020 10:07:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-21T05:07:10', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '91eb38b9-e21a-4dc9-adab-110261feb54f' User entered 'No (N)'	System	21 Dec 2020 10:07:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-21T05:07:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '91eb38b9-e21a-4dc9-adab-110261feb54f' User entered '21 Dec 2020 05:07:14'	System	21 Dec 2020 10:07:19
	System	21 Dec 2020 10:07:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-28T14:34:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '246e906f-9ce3-4077-b366-05de4ab5d17c' User entered 'No (N)'	System	28 Dec 2020 19:34:25
	System	28 Dec 2020 19:34:25

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-28T14:34:20', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '246e906f-9ce3-4077-b366-05de4ab5d17c' User entered 'No (N)'	System	28 Dec 2020 19:34:25

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2020-12-28T14:34:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '246e906f-9ce3-4077-b366-05de4ab5d17c' User entered '28 Dec 2020 14:34:23'	System	28 Dec 2020 19:34:25
	System	28 Dec 2020 19:34:25

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-05T11:09:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f50fbb10-89a6-46c4-8efb-af3d0939663d' User entered 'No (N)'	System	05 Jan 2021 16:09:54
	System	05 Jan 2021 16:09:54

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-05T11:09:46', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f50fbb10-89a6-46c4-8efb-af3d0939663d' User entered 'No (N)'	System	05 Jan 2021 16:09:54

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-05T11:09:50', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'f50fbb10-89a6-46c4-8efb-af3d0939663d' User entered '05 Jan 2021 11:09:50'	System	05 Jan 2021 16:09:54
	System	05 Jan 2021 16:09:54

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-11T14:38:05', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e946b66a-9b93-4dc8-b605-b06af0ce5212' User entered 'No (N)'	System	11 Jan 2021 19:38:16
	System	11 Jan 2021 19:38:16

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-11T14:38:09', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e946b66a-9b93-4dc8-b605-b06af0ce5212' User entered 'No (N)'	System	11 Jan 2021 19:38:16
	System	11 Jan 2021 19:38:16

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-11T14:38:12', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e946b66a-9b93-4dc8-b605-b06af0ce5212' User entered '11 Jan 2021 14:38:12'	System	11 Jan 2021 19:38:16
	System	11 Jan 2021 19:38:16

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-18T16:41:22', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'dbe03536-709c-4989-a17d-6f72cdbc39d8'	System	20 Jan 2021 15:58:07
User entered 'No (N)'	System	20 Jan 2021 15:58:07

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-18T16:41:26', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'dbe03536-709c-4989-a17d-6f72cdbc39d8'	System	20 Jan 2021 15:58:07
User entered 'No (N)'	System	20 Jan 2021 15:58:07

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-18T16:41:29', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'dbe03536-709c-4989-a17d-6f72cdbc39d8'	System	20 Jan 2021 15:58:07
User entered '18 Jan 2021 16:41:29'	System	20 Jan 2021 15:58:07

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-25T03:48:36', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e62d90f9-f5c0-4942-b3fa-25766acf55d2'	System	25 Jan 2021 08:48:50
User entered 'No (N)'	System	25 Jan 2021 08:48:50

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-25T03:48:42', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e62d90f9-f5c0-4942-b3fa-25766acf55d2'	System	25 Jan 2021 08:48:50
User entered 'No (N)'	System	25 Jan 2021 08:48:50

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-01-25T03:48:45', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'e62d90f9-f5c0-4942-b3fa-25766acf55d2' User entered '25 Jan 2021 03:48:45'	System	25 Jan 2021 08:48:50
	System	25 Jan 2021 08:48:50

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-04T15:07:31', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6eb4b032-93ee-49e6-885d-81b07844b723' User entered 'No (N)'	System	04 Feb 2021 20:07:41
	System	04 Feb 2021 20:07:41

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-04T15:07:34', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6eb4b032-93ee-49e6-885d-81b07844b723'	System	04 Feb 2021 20:07:41
User entered 'No (N)'	System	04 Feb 2021 20:07:41

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-04T15:07:38', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '6eb4b032-93ee-49e6-885d-81b07844b723' User entered '04 Feb 2021 15:07:38'	System	04 Feb 2021 20:07:41
	System	04 Feb 2021 20:07:41

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-08T02:57:04', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '31d2481b-387f-442d-9dfd-8793cc6ae3ff' User entered 'No (N)'	System	11 Feb 2021 17:57:28
	System	11 Feb 2021 17:57:28

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-08T02:57:08', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '31d2481b-387f-442d-9dfd-8793cc6ae3ff' User entered 'No (N)'	System	11 Feb 2021 17:57:28
	System	11 Feb 2021 17:57:28

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-08T02:57:12', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '31d2481b-387f-442d-9dfd-8793cc6ae3ff' User entered '08 Feb 2021 02:57:12'	System	11 Feb 2021 17:57:28
	System	11 Feb 2021 17:57:28

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-15T00:02:33', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63647c3e-8b14-4712-b7bd-c201987fe03e' User entered 'No (N)'	System	15 Feb 2021 05:03:14
	System	15 Feb 2021 05:03:14

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-15T00:02:37', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63647c3e-8b14-4712-b7bd-c201987fe03e' User entered 'No (N)'	System	15 Feb 2021 05:03:14
	System	15 Feb 2021 05:03:14

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-15T00:02:40', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '63647c3e-8b14-4712-b7bd-c201987fe03e' User entered '15 Feb 2021 00:02:40'	System	15 Feb 2021 05:03:14
	System	15 Feb 2021 05:03:14

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-22T03:55:14', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '3941116c-fcb9-4056-a0f6-3420b647b324' User entered 'No (N)'	System	22 Feb 2021 08:55:27
	System	22 Feb 2021 08:55:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-22T03:55:18', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '3941116c-fcb9-4056-a0f6-3420b647b324' User entered 'No (N)'	System	22 Feb 2021 08:55:27
	System	22 Feb 2021 08:55:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-02-22T03:55:23', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '3941116c-fcb9-4056-a0f6-3420b647b324' User entered '22 Feb 2021 03:55:23'	System	22 Feb 2021 08:55:27
	System	22 Feb 2021 08:55:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-03T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '07fa34b9-5f28-41a9-b003-c5792f292488'	System	03 Mar 2021 17:03:27
User entered 'No (N)'	System	03 Mar 2021 17:03:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-03T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '07fa34b9-5f28-41a9-b003-c5792f292488'	System	03 Mar 2021 17:03:27
User entered 'No (N)'	System	03 Mar 2021 17:03:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-03T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '07fa34b9-5f28-41a9-b003-c5792f292488' User entered '03 Mar 2021 12:00:33'	System	03 Mar 2021 17:03:27
	System	03 Mar 2021 17:03:27

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-08T04:41:47-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '916ced1f-d97d-4ee2-afed-94d5ac21ef32'	System	08 Mar 2021 09:41:56
User entered 'No (N)'	System	08 Mar 2021 09:41:56

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-08T04:41:51-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '916ced1f-d97d-4ee2-afed-94d5ac21ef32'	System	08 Mar 2021 09:41:56
User entered 'No (N)'	System	08 Mar 2021 09:41:56

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-08T04:41:54-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '916ced1f-d97d-4ee2-afed-94d5ac21ef32' User entered '08 Mar 2021 04:41:54'	System	08 Mar 2021 09:41:56
	System	08 Mar 2021 09:41:56

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:05:41-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered 'Yes (Y)'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:05:48-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered 'No (N)'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:05:54-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered 'No (N)'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:06:04-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered 'Yes (Y)'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:06:29-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-15T00:06:34-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '660938aa-6e82-46d0-9362-bdf84242b169'	System	15 Mar 2021 04:06:47
User entered '15 Mar 2021 00:06:34'	System	15 Mar 2021 04:06:47

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-22T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae906cb9-e63c-4011-ab38-e5af831738ae' User entered 'No (N)'	System	22 Mar 2021 04:03:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-22T00:02:30-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae906cb9-e63c-4011-ab38-e5af831738ae' User entered 'No (N)'	System	22 Mar 2021 04:03:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-22T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae906cb9-e63c-4011-ab38-e5af831738ae' User entered '22 Mar 2021 00:02:33'	System	22 Mar 2021 04:03:19
	System	22 Mar 2021 04:03:19

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-29T05:54:04-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae3c13f6-8eac-4670-a8d7-d3590f971933'	System	29 Mar 2021 09:54:15
User entered 'No (N)'	System	29 Mar 2021 09:54:15

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-29T05:54:07-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae3c13f6-8eac-4670-a8d7-d3590f971933'	System	29 Mar 2021 09:54:15
User entered 'No (N)'	System	29 Mar 2021 09:54:15

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-29T05:54:12-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ae3c13f6-8eac-4670-a8d7-d3590f971933' User entered '29 Mar 2021 05:54:12'	System	29 Mar 2021 09:54:15
	System	29 Mar 2021 09:54:15

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-07T12:32:04-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '776c6431-2009-4a60-a19a-eb3e55dbe321'	System	08 Apr 2021 16:13:46
User entered 'No (N)'	System	08 Apr 2021 16:13:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-07T12:32:08-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '776c6431-2009-4a60-a19a-eb3e55dbe321'	System	08 Apr 2021 16:13:46
User entered 'No (N)'	System	08 Apr 2021 16:13:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-07T12:32:11-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '776c6431-2009-4a60-a19a-eb3e55dbe321'	System	08 Apr 2021 16:13:46
User entered '07 Apr 2021 12:32:11'	System	08 Apr 2021 16:13:46

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-12T05:13:53-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ff9f7e8a-a5fc-4877-9249-07deb63986e9' User entered 'No (N)'	System	12 Apr 2021 09:14:09
	System	12 Apr 2021 09:14:09

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-12T05:13:59-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ff9f7e8a-a5fc-4877-9249-07deb63986e9' User entered 'No (N)'	System	12 Apr 2021 09:14:09

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-12T05:14:03-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'ff9f7e8a-a5fc-4877-9249-07deb63986e9'	System	12 Apr 2021 09:14:09
User entered '12 Apr 2021 05:14:03'	System	12 Apr 2021 09:14:09

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-19T05:18:29-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '39414211-4ea0-4881-9894-201521e3f23b'	System	19 Apr 2021 09:18:42
User entered 'No (N)'	System	19 Apr 2021 09:18:42

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-19T05:18:33-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '39414211-4ea0-4881-9894-201521e3f23b'	System	19 Apr 2021 09:18:42
User entered 'No (N)'	System	19 Apr 2021 09:18:42

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-19T05:18:37-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '39414211-4ea0-4881-9894-201521e3f23b' User entered '19 Apr 2021 05:18:37'	System	19 Apr 2021 09:18:42
	System	19 Apr 2021 09:18:42

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-28T12:00:23-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1f19b888-8609-4974-8275-1b4ab52d0ce1' User entered 'No (N)'	System	28 Apr 2021 23:18:36
	System	28 Apr 2021 23:18:36

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-28T12:00:26-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1f19b888-8609-4974-8275-1b4ab52d0ce1'	System	28 Apr 2021 23:18:36
User entered 'No (N)'	System	28 Apr 2021 23:18:36

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-04-28T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '1f19b888-8609-4974-8275-1b4ab52d0ce1'	System	28 Apr 2021 23:18:36
User entered '28 Apr 2021 12:00:29'	System	28 Apr 2021 23:18:36

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-05-03T00:24:20-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5a4833f5-40b2-4f3d-a55a-8b7fcef4d855'	System	03 May 2021 04:24:35
User entered 'No (N)'	System	03 May 2021 04:24:35

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

Have you been exposed to someone with 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 (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-05-03T00:24:27-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5a4833f5-40b2-4f3d-a55a-8b7fcef4d855'	System	03 May 2021 04:24:35
User entered 'No (N)'	System	03 May 2021 04:24:35

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-05-03T00:24:31-04:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: '5a4833f5-40b2-4f3d-a55a-8b7fcef4d855'	System	03 May 2021 04:24:35
User entered '03 May 2021 00:24:31'	System	03 May 2021 04:24:35

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:05:51

US3432240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:51
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:05:51

US3432240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-03T12:01:27-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bb147ebc-628a-4e75-9f6c-be4b1e42aa4b'	System	03 Mar 2021 17:14:29
User entered 'No (N)'	System	03 Mar 2021 17:14:29

US3432240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:40

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA71E578-4481-4832-98DF-9330DB3AA3D9)', Time: '2021-03-03T12:01:31-05:00', User OID: 'PatientReportedOutcome (US3432240)', ODM File OID: 'bb147ebc-628a-4e75-9f6c-be4b1e42aa4b' User entered '03 Mar 2021 12:01:31'	System	03 Mar 2021 17:14:29
	System	03 Mar 2021 17:14:29

US3432240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:57:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 16:22:16

US3432240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:57:10
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 16:22:16

US3432240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:57:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Nov 2020 16:22:16

US3432240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:55:58
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:57:10
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 16:22:16

US3432240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:56:02
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:57:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 16:22:20

US3432240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	21 Apr 2021 22:05:31
Data hard unlocked.	(b) (4), (b) (6)	20 Apr 2021 22:56:02
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:44:08
User entered 'l'	System	18 Nov 2020 16:22:20

US3432240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	21 Dec 2020 19:54:31

US3432240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '21 Dec 2020'	Kathleen Garvey (b) (4)	21 Dec 2020 19:54:31

US3432240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	21 Dec 2020 19:54:31

US3432240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered empty.	Kathleen Garvey (b) (4)	21 Dec 2020 19:54:31

US3432240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	21 Dec 2020 19:54:35

US3432240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
User entered 'I'	System	21 Dec 2020 19:54:35

US3432240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 15:55:00

US3432240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 15:55:00

US3432240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 15:55:00

US3432240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 15:55:00

US3432240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 15:55:07

US3432240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
User entered 'I'	System	20 Jan 2021 15:55:07

US3432240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	23 Feb 2021 17:07:40

US3432240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '23 Feb 2021'	Tenaizus Woods (b) (4)	23 Feb 2021 17:07:40

US3432240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	23 Feb 2021 17:07:40

US3432240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty.	Tenaizus Woods (b) (4)	23 Feb 2021 17:07:40

US3432240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	23 Feb 2021 17:07:45

US3432240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:09:03
User entered 'I'	System	23 Feb 2021 17:07:45

US3432240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 14:36:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '31 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 14:36:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:14:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Mar 2021 14:36:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 14:36:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User entered '31 Mar 2021' reason for change: Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:06
User entered '31 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User entered '10:05' reason for change: Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:06
User entered '10:05'	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:05'	System	15 Apr 2021 16:42:23
User entered empty.	System	31 Mar 2021 14:45:06
User entered '31 Mar 2021 10:05'	System	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User entered '36.5' C reason for change: Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:06
User entered '36.5' C	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:23
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Apr 2021 16:42:45
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:45:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:41:35
User entered 'N/A' (non-conformant).	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 16:42:45
User entered empty.	System	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Apr 2021 16:42:45
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:45:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:41:35
User entered 'N/A' (non-conformant).	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 16:42:45
User entered empty.	System	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Apr 2021 16:42:45
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:45:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:41:35
User entered 'N/A' (non-conformant).	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 16:42:45
User entered empty.	System	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Apr 2021 16:42:45
Signature has been broken.	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jun Bai Park Chang	15 Apr 2021 16:42:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 16:42:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:45:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:45:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Mar 2021 14:41:35
User entered 'N/A' (non-conformant).	(b) (4), (b) (6)	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 16:42:45
User entered empty.	System	31 Mar 2021 14:41:35

US3432240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:44:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 14:43:06

US3432240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:44:57
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 14:43:06

US3432240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 14:45:40

US3432240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '31 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 14:45:40

US3432240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '10:20'	(b) (4), (b) (6)	31 Mar 2021 14:45:40

US3432240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:20'	System	31 Mar 2021 14:45:40

US3432240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:04:55
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 14:45:46

US3432240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 14:45:46

US3432240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:09:06
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	20 Apr 2021 19:22:48

US3432240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 04:35:20
	(b) (4)	
Signature has been broken.	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
	(b) (4)	
User entered '26 Apr 2021' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4)	
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 19:22:48
	(b) (4)	

US3432240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 04:35:20
	(b) (4)	
Signature has been broken.	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	20 Apr 2021 19:22:48
	(b) (4)	

US3432240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 04:35:20
	(b) (4)	
Signature has been broken.	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
	(b) (4)	
User entered empty; reason for change Data Entry Error	Tenaizus Woods (b) (4)	26 Apr 2021 13:43:56
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4)	
User entered 'Pt unavailable'	(b) (4), (b) (6)	20 Apr 2021 19:22:48
	(b) (4)	

US3432240

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	28 Apr 2021 04:35:20
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	26 Apr 2021 13:44:16

US3432240

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 13:44:16

US3432240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:10:55

US3432240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '6 Jan 2021'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:10:55

US3432240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:10:55

US3432240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 20:10:55

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '6 Jan 2021'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:44:17
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 17:56:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:46

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:44:17
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 17:56:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:46

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '6 Jan 2021'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:03:38
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:03:38
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'No (N)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User entered empty.	System	06 Jan 2021 20:12:16

US3432240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:40

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User entered empty.	System	06 Jan 2021 20:12:16

US3432240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:31

US3432240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '6 Jan 2021'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:31

US3432240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '10:40'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:31

US3432240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User entered '6 Jan 2021 10:40'	System	06 Jan 2021 20:12:31

US3432240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:44

US3432240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '6 Jan 2021'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:44

US3432240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User entered '10:44'	Natalie Izaguirre (b) (4)	06 Jan 2021 20:12:44

US3432240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:13
User entered '6 Jan 2021 10:44'	System	06 Jan 2021 20:12:44

US3432240

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:36:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:56:34
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:03:15

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Flushing, LLT: Facial flushing - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:05:46
Data point term sent to Coder	System	31 Aug 2020 14:05:27
User entered 'Facial Flushing'	Phoebe Cunningham	31 Aug 2020 14:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '14:00'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User entered '22 Aug 2020 14:00'	System	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '23:00'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User entered '22 Aug 2020 23:00'	System	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'Related (RELATED)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'None (NONE)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'I'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered '0'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 22:09:28
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User entered '0'	System	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42
User entered '0'	System	31 Aug 2020 14:05:09

US3432240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:21:42

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:30:27
User entered	System	17 Mar 2021 15:30:07
'USA-US078-2021-mRNA-1273-P301000018'		
User entered 'New'	(b) (4), (b) (6)	17 Mar 2021 15:30:07

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Arthritis bacterial, LLT: Septic arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 09:14:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 09:14:45
	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 13:29:31
User entered 'L shoulder septic arthritis'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'No (N)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	14 Apr 2021 15:25:38
DataPoint Verified.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
User entered 'No (N)'	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:05:38
User entered '08 Mar 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Apr 2021 17:12:11
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '03 Mar 2021'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 13:28:45

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:59:48
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
	(b) (4)	
User entered 'Yes (Y)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:59:57
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
	(b) (4)	
User entered '19 Apr 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
	(b) (4)	
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[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)	29 Apr 2021 15:47:40
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 Mar 2021 20:17:20
User entered empty.	System	16 Mar 2021 13:28:45

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:44:49
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	14 Apr 2021 15:25:38
DataPoint Verified.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
User entered 'Yes (Y)'	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'I'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '08 Mar 2021'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '12 Mar 2021'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'No (N)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
User closed query 'PV Query: Please specify the antibiotics that were given to the subject as treatment for the event, in the concomitant section of the CRF. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:50:32
Query 'PV Query: Please specify the antibiotics that were given to the subject as treatment for the event, in the concomitant section of the CRF. ' answered with 'updated con meds' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User opened query 'PV Query: Please specify the antibiotics that were given to the subject as treatment for the event, in the concomitant section of the CRF. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:16:57
User entered 'I'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, HARDWARE REMOVED. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:48:21
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, HARDWARE REMOVED. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'please see this has been added to con procedures' (Site from DM).	Monica Feeley (b) (4)	20 Apr 2021 16:46:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, HARDWARE REMOVED. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:13:51
User entered 'I'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:00:06
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Monica Feeley (b) (4)	21 Apr 2021 16:44:58
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
	(b) (4), (b) (6)	
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)	01 Apr 2021 14:05:57
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 'confirmed with pt during their v4 that they are still recovering/resolving from this event' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 14:35:10
	(b) (4), (b) (6)	
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)	23 Mar 2021 20:17:07
	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:28:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:36:40

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	21 Apr 2021 13:50:49
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:50:42
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)	21 Apr 2021 08:48:31
User closed query 'Per DM CLR: Narrative = 8MAR2021 FOR ELECTIVE ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'records have been sent' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:02:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'no relevant laboratory or diagnostic test results' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 16:45:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:25:38
Query 'Per DM CLR: Narrative = 8MAR2021 FOR ELECTIVE ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'that is correct, because the elective rotator cuff repair never occurred. they saw the infection and removed the hardware instead. we can add this to con procedures' (Site from DM).	Monica Feeley (b) (4)	07 Apr 2021 21:45:01

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:06:03
User closed query 'PV Query: Did the subject had any signs/symptoms? If yes, then please detail the course of the event. If no, then please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:06:00
User opened query 'Per DM CLR: Narrative = 8MAR2021 FOR ELECTIVE ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:13:36
User entered 'ADMITTED 8MAR2021 FOR ELECTIVE ROTATOR CUFF REPAIR. FOUND TO HAVE PURULENCE FROM PROXIMAL HUMERUS AND GH JOINT. HARDWARE REMOVED. STARTED TREATMENT WITH ANTIBIOTICS. No signs or symptoms of infection.' reason for change: New Information	Monica Feeley (b) (4)	31 Mar 2021 23:13:21
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'underlying risk factor is the L shoulder fracture captured in medical history. This fracture lead to the placement of the hardware. Medical hardware becomes infected, so this is the risk factor. ' (Site from Safety).	Monica Feeley (b) (4)	31 Mar 2021 23:10:53
Query 'PV Query: Did the subject had any signs/symptoms? If yes, then please detail the course of the event. If no, then please state so. ' answered with 'confirmed with pt during their visit that the infection they had during the surgery was unexpected and experienced no previous symptoms ' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 14:36:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:17:43

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Mar 2021 20:17:34
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:17:27
Query 'PV Query: Please specify the antibiotics that were given to the subject as treatment for the event, in the concomitant section of the CRF. ' canceled (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:16:50
User opened query 'PV Query: Please specify the antibiotics that were given to the subject as treatment for the event, in the concomitant section of the CRF. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:16:44
User opened query 'PV Query: Did the subject had any signs/symptoms? If yes, then please detail the course of the event. If no, then please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:16:35
User entered 'admitted 8MAR2021 for elective rotator cuff repair. Found to have purulence from proximal humerus and GH joint. Hardware removed. started treatment with antibiotics.'	Monica Feeley (b) (4)	16 Mar 2021 13:28:45

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 13:28:45

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 13:28:45

US3432240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 13:28:45

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User closed query 'Per CDM re-query: Response indicates "participant was taking ibuprofen". However Ibuprofen is recorded for "Dental Procedure" and there is no medication recorded for solicited event "Pain at injection site" for Dairy dose 2 Day 2 (26 SEP). Please confirm if ibuprofen was taken for pain at injection site as well. If yes, add the medication with the indication for timeframe recorded per eDiary. Else confirm no medication taken in query response. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:36:47
Query 'Per CDM re-query: Response indicates "participant was taking ibuprofen". However Ibuprofen is recorded for "Dental Procedure" and there is no medication recorded for solicited event "Pain at injection site" for Dairy dose 2 Day 2 (26 SEP). Please confirm if ibuprofen was taken for pain at injection site as well. If yes, add the medication with the indication for timeframe recorded per eDiary. Else confirm no medication taken in query response. ' answered with 'no medication reported for injection site pain in eDiary or safety call 36. only ibuprofen reported for dental procedure.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 20:09:40
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:04:36

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Query 'Per CDM re-query: Response indicates "participant was taking ibuprofen". However Ibuprofen is recorded for "Dental Procedure" and there is no medication recorded for solicited event "Pain at injection site" for Dairy dose 2 Day 2 (26 SEP). Please confirm if ibuprofen was taken for pain at injection site as well. If yes, add the medication with the indication for timeframe recorded per eDiary. Else confirm no medication taken in query response. ' canceled (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:04:33
User opened query 'Per CDM re-query: Response indicates "participant was taking ibuprofen". However Ibuprofen is recorded for "Dental Procedure" and there is no medication recorded for solicited event "Pain at injection site" for Dairy dose 2 Day 2 (26 SEP). Please confirm if ibuprofen was taken for pain at injection site as well. If yes, add the medication with the indication for timeframe recorded per eDiary. Else confirm no medication taken in query response. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:03:53
User opened query 'Per CDM re-query: Response indicates "participant was taking ibuprofen". However Ibuprofen is recorded for "Dental Procedure" and there is no medication recorded for solicited event "Pain at injection site" for Dairy dose 2 Day 2 (26 SEP). Please confirm if ibuprofen was taken for pain at injection site as well. If yes, add the medication with the indication for timeframe recorded per eDiary. Else confirm no medication taken in query response. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:03:46
Query 'Per DM CLR: Per Dairy Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'participant was taking ibuprofen during this time. Already indicated on the con meds eCRF. Thank you' (Site from DM).	Bruce Bausk (b) (4) (b) (4)	10 Mar 2021 17:23:29

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:55:49
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:52:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:00:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 18:06:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 18:06:15
Data point term sent to Coder User entered 'Lipitor'	System (b) (4), (b) (6)	22 Aug 2020 18:05:25 22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'High Cholesterol'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '10'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'UN UNK 2005'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 18:05:14

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:07:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:07:15
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 18:06:26
User entered 'Omeprazole'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	16 Nov 2020 16:46:54
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:26
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' answered with 'Has been updated' (Site from DM).	Megan Powell (b) (4)	22 Oct 2020 18:19:30
DataPoint Un-verified.	(b) (4)	22 Oct 2020 18:19:18
User entered 'No (N)' reason for change: Data Entry Error	Megan Powell (b) (4)	22 Oct 2020 18:19:18
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:17:51
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'GERD'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '20'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'as needed (PRN)' reason for change:	(b) (4), (b) (6)	22 Aug 2020 18:10:31
Data Entry Error		
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'UN UNK 2010'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition started prior ICF and indication of 'GERD' does not reflect one of the Solicited Events for the study . Review and update entry as appropriate.	(b) (4), (b) (6)	01 Oct 2020 09:44:37
' canceled (Site from DM).		
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition started prior ICF and indication of 'GERD' does not reflect one of the Solicited Events for the study . Review and update entry as appropriate.	(b) (4), (b) (6)	01 Oct 2020 09:44:01
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:31
	(b) (4), (b) (6)	
User closed query 'Please check and confirm response.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 03:09:30
Query 'Please check and confirm response.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	07 Sep 2020 21:47:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	07 Sep 2020 21:47:01
	(b) (4)	
User opened query 'Please check and confirm response.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 21:56:07
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:06:20
	(b) (4), (b) (6)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:10:31
User entered '1'	System	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:10:31
User entered '1'	System	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:10:31
User entered '804 (804)'	System	22 Aug 2020 18:06:20

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
	(b) (4)	
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:10:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:10:17
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 18:09:31
User entered 'Vitamin D'	(b) (4), (b) (6)	22 Aug 2020 18:08:31
	(b) (4), (b) (6)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'General Health'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '1000'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'IU (IU)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	24 Aug 2020 23:52:17
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'UN UNK 2015'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 18:08:31

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:11:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:11:18
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 18:10:33
Data point term sent to Coder	System	22 Aug 2020 18:09:31
User entered 'Cialis'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:47:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:55
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' answered with 'Has been updated' (Site from DM).	Megan Powell (b) (4)	22 Oct 2020 18:20:33
DataPoint Un-verified.	(b) (4)	22 Oct 2020 18:20:27
User entered 'No (N)' reason for change: Data Entry Error	Megan Powell (b) (4)	22 Oct 2020 18:20:27
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:17:59
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 18:09:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 18:09:48
User entered 'Erectile Dysfunction' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 18:09:48
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 18:09:28
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '5'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:02
	(b) (4), (b) (6)	
User closed query 'Con-med- Cialis- Start date- UN UNK 2020- Per source start date is UN May 2020, please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 03:09:51
Query 'Con-med- Cialis- Start date- UN UNK 2020- Per source start date is UN May 2020, please check and confirm.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	07 Sep 2020 21:48:47
	(b) (4)	
User entered 'UN May 2020' reason for change:	Monica Feeley (b) (4)	07 Sep 2020 21:48:40
Data Entry Error	(b) (4)	
User opened query 'Con-med- Cialis- Start date- UN UNK 2020- Per source start date is UN May 2020, please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 21:57:57
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 21:57:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
	(b) (4), (b) (6)	
User entered 'UN UNK 2020'	(b) (4), (b) (6)	22 Aug 2020 18:09:28
	(b) (4), (b) (6)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:55:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 18:09:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:49:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:49:48
Data point term sent to Coder	System	25 Sep 2020 17:49:21
User entered 'Amoxicillin'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Dental procedure'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '875'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 14:27:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '29 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 14:27:19
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:27:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User entered '2'	System	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User entered '1'	System	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:11
User entered '804 (804)'	System	25 Sep 2020 17:49:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:26:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:26:41
Data point term sent to Coder	System	25 Sep 2020 17:50:26
User entered 'Ibuprofen'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Dental procedure'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '400'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:59:44
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:29:57
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:33:02
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:32:37
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 21:32:37
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:06:54
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:27:54
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 20:00:06
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:32:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 21:32:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '4 times per day' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:27:54
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
User closed query 'Per CDM RQ: Response noted. Please review and confirm if medication remains ongoing once known. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 05:52:06
Query 'Per CDM RQ: Response noted. Please review and confirm if medication remains ongoing once known. Thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 19:58:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 16:25:32
User opened query 'Per CDM RQ: Response noted. Please review and confirm if medication remains ongoing once known. Thank you.' (Site from DM). User closed query 'Per DM CLR: Please review and confirm if medication remains ongoing as the procedure is already done and it is unlikely for the medication to remain ongoing for an extended period of time. Please update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:25:22
Query 'Per DM CLR: Please review and confirm if medication remains ongoing as the procedure is already done and it is unlikely for the medication to remain ongoing for an extended period of time. Please update as appropriate, otherwise clarify.' answered with 'need to discuss with participant' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:30:35
User opened query 'Per DM CLR: Please review and confirm if medication remains ongoing as the procedure is already done and it is unlikely for the medication to remain ongoing for an extended period of time. Please update as appropriate, otherwise clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:30:35
	Monica Feeley (b) (4)	12 Nov 2020 20:24:20
	(b) (4), (b) (6)	12 Nov 2020 18:46:12
	(b) (4), (b) (6)	03 Nov 2020 17:54:28

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:58:30
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 16:25:22
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 16:25:22
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:58:42
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:09:26
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	12 Nov 2020 20:24:25
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	12 Nov 2020 20:23:49
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:32
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:53:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User entered '4'	System	23 Nov 2020 21:32:37
User entered empty.	System	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User entered '1'	System	23 Nov 2020 21:32:37
User entered empty.	System	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:19
User entered '804 (804)'	System	23 Nov 2020 21:32:37
User entered empty.	System	25 Sep 2020 17:50:25

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:48:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:48:43
Data point term sent to Coder	System	02 Oct 2020 14:29:43
User entered 'CLindamycin'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'dental implant'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '300'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '30 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 14:14:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '6 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 14:14:33
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User entered '2'	System	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User entered '1'	System	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:29
User entered '804 (804)'	System	02 Oct 2020 14:29:05

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
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)	29 Oct 2020 19:47:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:47:46
Data point term sent to Coder	System	28 Oct 2020 18:20:44
User entered 'influenza vaccination'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'prophylaxis'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '0.5'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'mL (mL)'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'once (ONCE)'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 18:20:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 18:20:13
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	28 Oct 2020 18:20:13
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 18:20:04
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '1 Sep 2020'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '0'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered '1 Sep 2020'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:54:28
User entered 'No (N)'	Julia Klopfer (b) (4)	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User entered empty.	System	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User entered empty.	System	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:39:37
User entered empty.	System	28 Oct 2020 18:20:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 07:11:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 07:11:02
Data point term sent to Coder	System	20 Apr 2021 19:34:22
User entered 'Vancomycin'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'L shoulder septic arthritis'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered '1000'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'three times daily (TID)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered '19 Mar 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered '0'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered '16 Apr 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:28
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User entered '3'	System	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User entered '1'	System	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:39
User entered '804 (804)'	System	20 Apr 2021 19:33:53

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:40:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:40:41
Data point term sent to Coder	System	20 Apr 2021 19:35:23
User entered 'Ceftriaxone'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'L shoulder septic arthritis'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered '2'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'g (g)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'once daily (QD)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered '08 Mar 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered '0'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:41:58
User closed query 'Per source is 20-Apr-21. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:41:45
Query 'Per source is 20-Apr-21. Please verify and update. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	21 Apr 2021 19:58:29
User entered '20 Apr 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Apr 2021 19:58:24
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User opened query 'Per source is 20-Apr-21. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:43:45
User entered '16 Apr 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:31
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User entered '1'	System	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User entered '1'	System	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:47
User entered '804 (804)'	System	20 Apr 2021 19:34:32

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 07:11:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 07:11:02
Data point term sent to Coder	System	20 Apr 2021 19:35:23
User entered 'Vancomycin'	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'L shoulder septic arthritis'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered '1500'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'mg (mg)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'three times daily (TID)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered empty.	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered '08 Mar 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered '0'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered '19 Mar 2021'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:23
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User entered '3'	System	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User entered '1'	System	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:51
User entered '804 (804)'	System	20 Apr 2021 19:35:04

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	21 Apr 2021 19:46:09
DataPoint Verified.	Coder Import (b) (4)	21 Apr 2021 16:59:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 16:59:46
Data point term sent to Coder	System	21 Apr 2021 16:46:56
User entered 'Tylenol'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'No (N)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'L shoulder rotator cuff repair'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered '1000'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'mg (mg)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'three times daily (TID)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered '20 Apr 2021'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'Yes (Y)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:09
User entered 'No (N)'	Monica Feeley (b) (4)	21 Apr 2021 16:46:45
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 16:46:45

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 16:46:45

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 16:46:45

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
	(b) (4), (b) (6)	21 Apr 2021 19:46:55
DataPoint Verified.	Coder Import (b) (4)	21 Apr 2021 17:02:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 17:02:38
Data point term sent to Coder User entered 'Dilaudid'	System Monica Feeley (b) (4)	21 Apr 2021 16:48:58 21 Apr 2021 16:48:46

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'No (N)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'L shoulder rotator cuff repair'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered '2-4'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'mg (mg)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'other (OTHER)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered '6x daily PRN'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered '20 Apr 2021'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered '0'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'Yes (Y)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered empty.	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:46:55
User entered 'No (N)'	Monica Feeley (b) (4)	21 Apr 2021 16:48:46
	(b) (4)	

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 16:48:46

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 16:48:46

US3432240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 16:48:46

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:36:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:58:50
User entered 'Yes (Y)' reason for change: New Information	Monica Feeley (b) (4)	03 Sep 2020 19:13:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 18:17:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:17:08

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:59:15
User entered '28 Aug 2020'	Monica Feeley (b) (4)	03 Sep 2020 19:13:52
	(b) (4)	

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:59:15
User entered 'Basal Cell Carcinoma removal surgery'	Monica Feeley (b) (4)	03 Sep 2020 19:13:52
	(b) (4)	

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:27:17
User closed query 'The reason for this procedure was Basal Cell Cancer Skin, so is the Indication which is mentioned in medical history . please check and edit. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:27:13
Query 'The reason for this procedure was Basal Cell Cancer Skin, so is the Indication which is mentioned in medical history . please check and edit. ' answered with 'this is what the EDC asks for' (Site from CRA).	Monica Feeley (b) (4)	12 Nov 2020 20:22:02
User opened query 'The reason for this procedure was Basal Cell Cancer Skin, so is the Indication which is mentioned in medical history . please check and edit. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:43:23
Query 'The reason for this procedure was Basal Cell Cancer Skin, so that will be medical history. please check and edit.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:42:45
User opened query 'The reason for this procedure was Basal Cell Cancer Skin, so that will be medical history. please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:41:09
User closed query 'Indication cannot be Medical History- Please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:41:09
Query 'Indication cannot be Medical History- Please check and confirm.' answered with 'Indication CAN be Medical History because participant was diagnosed with Basal Cell Cancer, as reported in medical history ' (Site from CRA).	Megan Powell (b) (4)	22 Oct 2020 18:17:35
User opened query 'Indication cannot be Medical History- Please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 21:59:46
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 21:59:18
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:59:15
User entered 'Medical History (MH)'	Monica Feeley (b) (4)	03 Sep 2020 19:13:52
	(b) (4)	

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:40

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 21:59:15
User entered empty.	Monica Feeley (b) (4)	03 Sep 2020 19:13:52
	(b) (4)	

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:21
User entered '12 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 17:27:32

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:23
User entered 'electromyography'	Phoebe Cunningham (b) (4)	12 Sep 2020 17:27:32

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:24
User entered 'Diagnostic (DIAGNOSTIC)'	Phoebe Cunningham (b) (4)	12 Sep 2020 17:27:32

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:26
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 17:27:32

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:46:32
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:49:27
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:47:41

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:46:33
User entered 'Dental implants'	(b) (4), (b) (6)	25 Sep 2020 17:47:41

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:46:35
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 17:47:41

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:36:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:10
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:46:37
User entered 'Reconstructive'	(b) (4), (b) (6)	25 Sep 2020 17:47:41

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:56
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:04:51
User entered '08 Mar 2021'	Monica Feeley (b) (4)	16 Apr 2021 17:11:30

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:56
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:04:51
User entered 'Removal of hardware in L shoulder'	Monica Feeley (b) (4)	16 Apr 2021 17:11:30

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:56
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:04:51
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	16 Apr 2021 17:11:30

US3432240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:36:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:12:56
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:04:51
User entered empty.	Monica Feeley (b) (4)	16 Apr 2021 17:11:30

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '17/Mar/2021 11:31'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered '01/Apr/2021 10:06'	System	01 Apr 2021 14:06:22

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:40

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)	21 Apr 2021 13:51:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 14:06:22

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:23:26
User entered '19/Apr/2021 06:18'	System	19 Apr 2021 13:18:10

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:51:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:23:26
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:18:10

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
User entered '21/Apr/2021 09:51'	System	21 Apr 2021 13:51:42

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:36:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 16:36:30
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 13:51:42

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 15:31:21
User entered 'USA-US078-2021-MRNA-1273-P301000018'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Yes (Y)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'No (N)'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Lindsey'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'Baden'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'MA'	System	17 Mar 2021 15:30:07

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:04:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:06:12
User entered 'US'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 16:31:17
User entered '4'	System	21 Apr 2021 13:51:42
User entered '3'	System	19 Apr 2021 13:18:10
User entered '2'	System	01 Apr 2021 14:06:22
User entered '1'	System	17 Mar 2021 15:31:38

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:36:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
User entered '22/Apr/2021 09:31'	System	22 Apr 2021 16:31:17

US3432240

Folder: SAE USA-US078-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:36:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 16:36:30
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 16:31:17